UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

THE METROHEALTH SYSTEM,

Plaintiff,

vs.

PURDUE PHARMA L.P., d/b/a PURDUE PHARMA (DELAWARE) LIMITED PARTNERSHIP; PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC.; ALLERGAN FINANCE, LLC f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC.; MALLINCKRODT LLC; and INSYS THERAPEUTICS, INC.,

Marketing Defendants,

- and -

JOHN KAPOOR; RICHARD SACKLER; THERESA SACKLER; KATHE SACKLER; JONATHAN SACKLER; MORTIMER D.A. SACKLER; BEVERLY SACKLER; DAVID SACKLER; and ILENE SACKLER LEFCOURT,

Individual Defendants.

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

COMPLAINT

DEMAND FOR JURY TRIAL

Filed on behalf of Plaintiff.

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COMPLAINT

Plaintiff, The MetroHealth System ("Plaintiff" or "MetroHealth"), a public health system in the State of Ohio, by and through its undersigned counsel, sues Defendants (defined below), and alleges as follows:

I. PRELIMINARY STATEMENT

1. Many communities in the United States, including Northeast Ohio and Cuyahoga County, which are served by MetroHealth, have experienced a stark increase in the number of their residents who have become addicted to prescription opioids and heroin, and a stark increase in opioid overdoses. Prescription opioids often serve as a "gateway" to heroin sold on the streets; approximately 80% of current heroin users got their start with prescription opioids.[1] Unlike any other epidemic, the opioid epidemic is largely man-made and has been created, fueled, and continues to expand by the continuing unlawful conduct of the defendant pharmaceutical manufacturers ("Marketing Defendants" – further defined below). Plaintiff brings this action for damages and injunctive relief to prevent future harm and to redress past wrongs.

2. A pharmaceutical manufacturer should never place its desire for profits above the health and well-being of its customers. Drug manufacturers have a legal duty to ensure their products are accompanied by full and accurate instructions and warnings to guide prescribing doctors and other healthcare providers in making treatment decisions. A pharmaceutical manufacturer has a legal duty to tell the truth when marketing its drugs and to ensure that its marketing claims are supported by science and medical evidence. Executives of a

[1] *Prescription Opioids and Heroin: Prescription Opioid Use is a Risk Factor for Heroin Use*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use (last updated January 2018).

pharmaceutical company, such as Individual Defendant John Kapoor ("Kapoor") and the Sackler Family Defendants (defined below), have a legal obligation to ensure that their company conducts itself in a manner that is both compliant with the law and designed to protect, rather than harm, patients. Defendants broke these simple rules.

3. Marketing Defendants knew that opioids were effective treatments for short-term use, such as post-surgical and trauma-related pain, and for end-of-life care. They also knew, or reasonably should have known, that prescription opioids are addictive and subject to abuse, particularly when used long-term for chronic non-cancer pain, and should be used with extreme caution and as a last resort. Defendants also knew, or reasonably should have known, that with prolonged use, tolerance to the pain relieving effect develops, the effectiveness of opioids decreases, requiring dosage increases to reduce pain, thereby increasing the risk of significant side effects and addiction. Defendants also knew that there were in existence no clinical trial results showing that opioids were safe and effective for long-term treatment of chronic pain, although they falsely represented that the appropriateness of such drugs for long-term use had been authoritatively established.

4. Prior to the mid-1990s, medical orthodoxy rejected the use of opioids as an accepted modality for the long-term treatment of chronic pain. The U.S. Food and Drug Administration ("FDA") has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use.[2]

5. In order to expand their market for opioids and realize blockbuster profits, Marketing Defendants needed to create a fundamental change in medical orthodoxy and public

[2] Janet Woodcock, *FDA/CDER Response to Physicians for Responsible Opioid Prescribing – Partial Petition Approval and Denial*, REGULATIONS.GOV (Sept. 10, 2013), https://www.regulations.gov/document?D=FDA-2012-P-0818-0793.

perception that would make opioids permissible and even the preferred treatment modality, not just for acute and palliative care, but also for long-term treatment of everyday aches and pains, like lower back pain, arthritis, headaches, and sports injuries.

6. Since the mid-1990s, the Marketing Defendants, led by the Purdue Pharma L.P. entities, have engaged in a scheme to boost sales for their prescription opioid products by upending medical orthodoxy and popular belief regarding the safety and efficacy of long-term opiate use. Defendants accomplished this reversal by falsely promoting their highly dangerous products for the use of chronic pain and knowingly, recklessly, and negligently, and with wanton disregard for the public health, denying or trivializing the risk of addiction.

7. In furtherance of their scheme, each Marketing Defendant expended millions of dollars and used the following unethical and unlawful methods to disseminate misinformation regarding the safety and efficacy of long-term opioid use for pain management treatment, including:

(a) paying doctors, called Key Opinion Leaders ("KOLs"), to give speeches and write misleading studies advocating the advantages of prescription opioids and to present deceptive continuing medical education programs ("CMEs") promulgating the message to fellow physicians that opioids are safe and effective for daily, long-term use;

(b) promoting the use of opioids for chronic pain through sales representatives, also called "detailers," whose jobs involved visiting individual physicians and their staff in their offices and setting up small group speaker programs. By establishing close relationships with doctors, the sales representatives were able to disseminate their misrepresentations in targeted one-on-one settings that allowed them to address and dispel individual prescribers' reservations about prescribing opioids for

chronic pain. Representatives were trained on techniques to build these relationships, with Marketing Defendant Actavis even rolling out an "Own the Nurse" kit as a "door opener" to time with doctors. Using the sales representatives as "foot soldiers" in the misinformation campaign, the Marketing Defendants were able to address individual prescribers' concerns about prescribing opioids for chronic pain and to push higher doses of the opioids, thereby driving up revenue.

(c) twisting scientific literature; most notably, transforming a five-sentence letter written to the NEW ENGLAND JOURNAL OF MEDICINE ("NEJM") in 1980 by Dr. Hershel Jick and his graduate assistant, Ms. Jane Porter ("Porter/Jick Letter"), regarding the relative safety of short-term opioid use by hospitalized patients, into a false assertion (cited more than 900 times) that the risk of addiction with long-term outpatient opioid use is less than 1%;

(d) infiltrating medical societies and CMEs with the false information that chronic pain could and should be safely and effectively treated with prescription opioids;

(e) using non-branded advertisements (that promote opioids generally, rather than any particular brand) disguised as educational materials for patients and prescribers, which are not regulated by the FDA, to falsely promise relief from pain with minimal side effects from opioids;

(f) providing organizations with official-sounding names, such as American Pain Foundation ("APF") (collectively such organizations are referred to as "Front Groups") with tens of millions of dollars to disseminate the falsehood that addiction is exceptionally rare and an easily handled risk of prescription opioids; and

(g) influencing consumers and the lay public, through magazine articles, newspaper stories, TV programs, etc. featuring KOLs and Front Groups regarding the falsely described advantages of opioids for chronic pain, with the specific intention and effect of recruiting patients to demand opioids from their treating physicians.

8. Defendants' actions are not permitted or excused by the fact that the FDA did not require that their products' labels specifically exclude the use of opioids for chronic pain. Accurate content on a label of a pharmaceutical product is squarely the responsibility of the pharmaceutical manufacturer. The FDA approval of their drugs for certain applications did not entitle Defendants to misrepresent the risks, benefits, or superiority of opioids. In fact, unlike any other prescription drugs that may have been marketed unlawfully in the past, opioids are highly addictive controlled substances. Thus, Marketing Defendants deceptively engaged – and in many instances profoundly harmed – a patient base that by definition was not able, biologically, to easily turn away from the drugs. These drugs would never have been prescribed in the first place, but for the Marketing Defendants' unlawful scheme.

9. Defendants' causal role is also not broken by the involvement of legitimate doctors writing opioid prescriptions for their patients. Defendants' ubiquitous marketing efforts and their deceptive messages tainted virtually every information source doctors could rely on and prevented these doctors from making informed treatment decisions. Defendants targeted not only pain specialists, but also primary care physicians, nurse practitioners, physician assistants, and other non-pain specialists who were even less likely to be able to assess the Defendants' misleading statements.

10. To the huge detriment of the health of Americans, Ohioans, and the patient population and geographical area served by MetroHealth, which includes Cuyahoga County, the

scheme of the Marketing Defendants (which was well-funded, well-organized, and pervasive) was extremely successful. In just a few years, the Marketing Defendants managed to jettison decades of well-established and sound medical orthodoxy holding that prescription opioids are far too addictive and potentially debilitating to be used to treat chronic pain. Marketing Defendants individually, and working together through their Front Groups and KOLs, persuaded doctors, patients, and even hospital accreditation bodies that what they had long known – that opioids are addictive drugs and should be used as a long-term treatment option only in very rare circumstances – was no longer true and that the opposite – the compassionate treatment of pain ***required*** opioids, the most superior pain management protocol – was the new truth.

11. For example, the Marketing Defendants, acting through one of their Front Groups, the APS, successfully introduced the "Pain as the Fifth Vital Sign" factor, which, along with respiration rate, body temperature, blood pressure, and pulse rate, is now considered a "vital sign" upon which doctors assess patients.[3] The Pain as a Fifth Vital Sign campaign was adopted by the Veterans Administration and Joint Commission (responsible for accreditation of hospitals including MetroHealth), both of which had extensive financial relationships with Purdue at the time of the roll-out of the campaign. To this day, federal funding of hospitals, including MetroHealth, is affected by how patients rate the hospital on the measurement of "pain control." Due to the Marketing Defendants' false campaign, many patients have come to expect a standard of "no pain at all" without understanding the medical risks of taking opioids at sufficiently high levels to achieve a zero-pain threshold. Thus, hospitals throughout the country, including

[3] *See* Natalia E. Morone, M.D. & Deborah K. Weiner, M.D., *Pain as the 5th Vital Sign: Exposing the Vital Need for Pain Education*, 35 Clinical Therapeutics 1728, 1729 (2013). In 2016, the American Medical Association recommended removing pain as the fifth vital sign. *See* Joyce Frieden, *Remove Pain as 5th Vital Sign, AMA Urged*, MEDPAGE TODAY (June 13, 2016), https://www.medpagetoday.com/meetingcoverage/ama/58486 ("'Just as we now know earth [is] not flat, we know that pain is not a vital sign.'").

MetroHealth, are forced to fail patient expectations and sacrifice federal funds in order to protect patients' safety by using opioids cautiously, if at all, and insisting that the pain control standard be brought to "tolerable" rather than "zero."

12. As a result of the Marketing Defendants' unlawful scheme, their profits skyrocketed. Opioid sales have steadily risen, from $3.8 billion in 2000 to $8 billion in 2010 to $9.6 billion in 2015. Purdue has earned more than ***$35 billion*** in opioid profits since 1996, including more than $3 billion in 2015 (from $800 million in 2006); Purdue's OxyContin sales rose from $45 million in 1996 to $3.1 billion in 2010. In addition, Endo Pharmaceuticals, Inc. reaped revenues of $1.15 billion from Opana ER alone from 2010 to 2013.

13. The explosion in opioid use and addiction, along with the corresponding explosion in profits for the Defendants, was not due to a medical breakthrough in pain treatment. Instead, it was due in substantial part – as the National Institutes of Health ("NIH") recognizes – to the "aggressive marketing" of Defendants. The NIH stated:

> Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and aggressive marketing by pharmaceutical companies.[4]

14. Over the past two decades, as the sales of opioids increased, so too did deaths, emergency room visits, and hospitalizations caused by opioids.[5]

15. Starting in or about 1996 – coinciding with a rapid increase in prescription opioid use for medical purposes, as more fully set forth *infra* – the United States has experienced an

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[4] *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing Before the U.S. S. Caucus on Int'l. Narcotics Control*, 113th Cong. 2 (2014) (testimony of Nora D. Volkow, M.D., Director, National Institute on Drug Abuse), *available at* https://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

[5] Andrew Kolodny, et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 ANNU. REV. PUB. HEALTH 559 (2015).

opioid epidemic which has been characterized as the worst drug epidemic in its history. An epidemic is defined as a sharp increase in the prevalence of a disease (or diseases) within a discreet period of time.[6] The principal disease associated with the opioid epidemic is opioid addiction, sometimes referred to as "opioid use disorder" or "opioid abuse or dependence."

16. The 2016 Guidelines issued by the U.S. Centers for Disease Control and Prevention ("CDC"), *CDC Guideline for Prescribing Opioids for Chronic Pain* (the "2016 CDC Guidelines"), is a peer-reviewed guideline based on scientific evidence. It has defined "opioid addiction," "opioid use disorder," and "opioid abuse or dependence" as a "problematic pattern of opioid use leading to clinically significant impairment or distress . . . manifested by specific criteria such as unsuccessful efforts to cut down or control use and use resulting in social problems and a failure to fulfill major role obligations at work, school, or home."[7]

17. Opioid addiction, like other forms of addiction, is a chronic medical condition. It is treatable, but not curable. Unfortunately, for a variety of reasons, including a shortage of and limitations on resources, the presence of shame and stigma, and the presence of barriers to treatment, only a small percentage of patients who need treatment actually receive the right types of treatment and levels of care, in the right settings, for the right lengths of time. In the absence

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[6] U.S. DEP'T OF HEALTH AND HUMAN SERVS., CTRS. FOR DISEASE CONTROL AND PREVENTION, PRINCIPLES OF EPIDEMIOLOGY IN PUBLIC HEALTH PRACTICE, AN INTRODUCTION TO APPLIED EPIDEMIOLOGY AND BIOSTATISTICS, 1-72 (3d ed. 2012), *available at* https://www.cdc.gov/ophss/csels/dsepd/ss1978/ss1978.pdf.

[7] Deborah Dowell, M.D., et al., *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, 65 MORBIDITY AND MORTALITY WKLY. REP. 1, 2 (2016). The current diagnostic manual used by most behavioral health professionals, DSM-V, uses the term "opioid use disorder" to refer to and define what has in the past essentially been referred to as opioid addiction. In this Complaint, Plaintiff will generally use the term "addiction" to refer to opioid use disorder, opioid addiction, and opioid abuse or dependence, unless context dictates otherwise. These diagnoses are "different from tolerance (diminished response to a drug with repeated use) and physical dependence (adaptation to a drug that produces symptoms of withdrawal when the drug is stopped)." *Id*.

of proper treatment, the disease of addiction is progressive and frequently fatal. Even with optimal treatment for the optimal time at the optimal setting, opioid addiction tends to be a relapsing disease.

18. Patients suffering from opioid use disorder or opioid abuse or dependence are at substantially higher risk for other diseases, such as HIV and hepatitis. In addition, as a result of their generally poor health, treatment of diseases that may be medically unrelated to their use, abuse, or dependence on opioids, such as diabetes, is generally more complex and costly, involving longer hospital stays.

19. According to the CDC, opioid addiction has led to an epidemic in opioid overdoses, in turn leading to an increase in opioid fatalities. In the period from 1994-2014, the CDC estimated that there were over 165,000 overdose deaths in the United States associated with prescription opioid use.[8] Public health authorities estimate that, for every opioid overdose death, there are 30 non-fatal overdoses.[9] Thus, in the period from 1999-2014, an estimated five million non-fatal opioid overdoses were also likely to have occurred.

20. In 2016, the CDC acknowledged the existence of two opioid epidemics involving: (1) addiction; and (2) overdoses. Also, in 2016, the President of the United States declared that an opioid and heroin epidemic exists in America.[10]

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[8] *Id.*, at 2, 18.

[9] Andrea Hsu, *Hospitals Could Do More for Survivors of Opioid Overdoses, Study Suggests*, NPR, Aug. 22, 2017, http://www.npr.org/sections/health-shots/2017/08/22/545115225/hospitals-could-do-more-for-survivors-of-opioid-overdoses-study-suggests.

[10] Dowell, et al., *supra* n.7, at 3, 34; *accord* Press Release, Ctrs. for Disease Control and Prevention, CDC launches campaign to help states fight prescription opioid epidemic (Sept. 25, 2017) (available at https://www.cdc.gov/media/releases/2017/p0925-rx-awareness-campaigns.html) [hereinafter "CDC Press Release, Sept. 25, 2017"] (recognizing "opioid epidemic"); *see* Proclamation No. 9499, 81 Fed. Reg. 65173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

21. The direct correlation between increases in sales of prescription opioids and opioid addiction and overdoses prompted the CDC and other public health authorities to conclude that the principal cause of both opioid epidemics was the unprecedented increase in use of prescription opioids.[11] The CDC gathered data relating to prescription opioid usage using sales of prescription opioids as a measure of prescription opioid usage and correlated this data with data relating to admissions for treatment of opioid use disorders and overdose deaths. Using this data and analysis, the CDC and other researchers concluded that the daily use of prescription opioids to treat chronic pain has been the principal causative factor driving both epidemics in opioid addiction and overdoses.[12]

22. Public health authorities have also concluded that prescription opioid use is responsible not only for the addiction and overdose epidemics relating directly to prescription opioids, but also for the multi-year surge in non-prescription, illegal opioid use, including the use of heroin and fentanyl. As law enforcement, public health authorities, and medical professionals have begun to limit the improper use of prescription opioids, and other changes (including the high price of prescription opioids) have reduced the supply of prescription opioids for legal use, many prescription opioid users suffering from opioid addiction have turned to heroin and fentanyl available on the black market.[13]

23. As the profits of the Defendants have increased year-after-year, so, too, have the numbers of substance abuse treatment admissions and overdose deaths in the State of Ohio.

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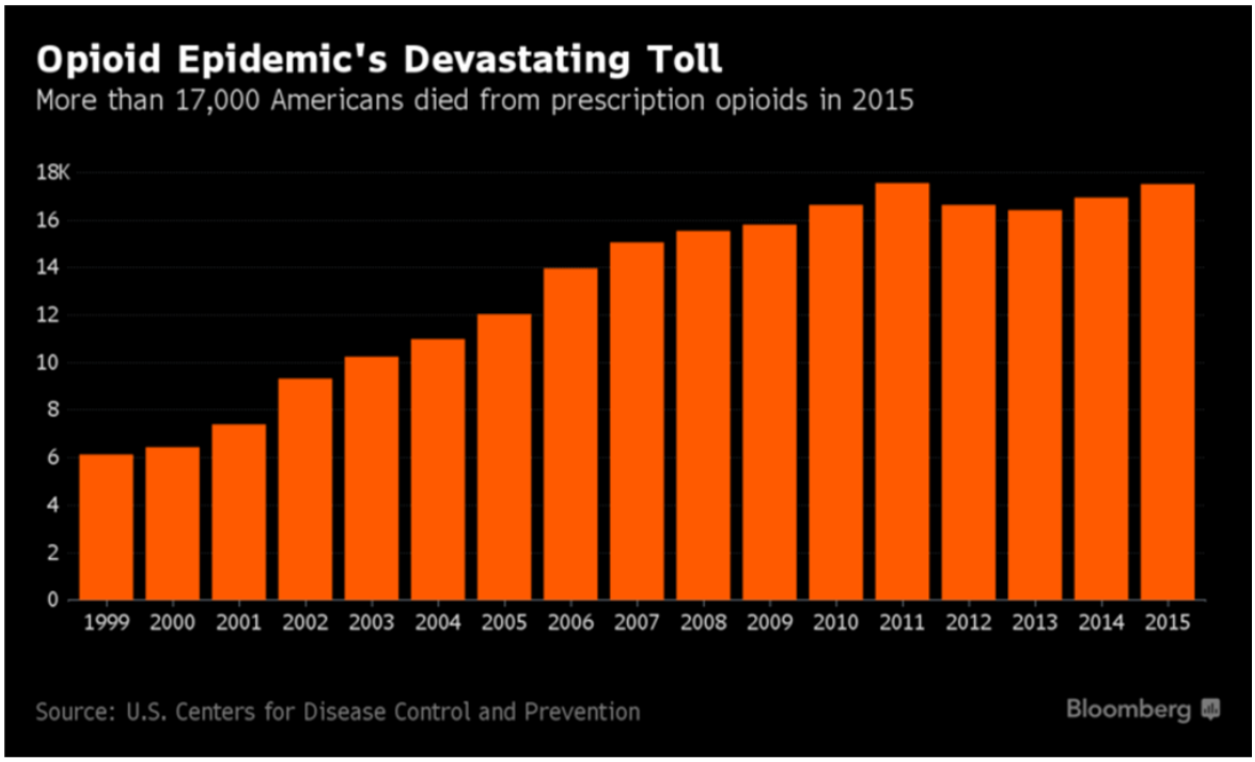
[11] Dowell, *et al.*, *supra* n.7, at 2.

[12] *Id.*

[13] Approximately 80% of individuals who begin using heroin made the transition from initial prescription opioids. See Kolodny, et al., *supra* n.5, at 560; *accord* THE MAYOR'S TASK FORCE TO COMBAT THE OPIOID EPIDEMIC IN PHILADELPHIA, FINAL REPORT AND RECOMMENDATIONS, at 7 (2017), *available at* http://dbhids.org/wp-content/uploads/2017/05/OTF_Report.pdf.

Ohio saw 4,050 drug-related overdose deaths in 2016, which equals almost 12 drug-related overdoses each day.[14] This constitutes a 32.8% increase in drug-related overdose deaths from 2015.[15]

24. The following chart from the CDC shows the steady increase of deaths related to prescription opioids nationally:



25. While the State of Ohio's skyrocketing drug overdose death rates follow a similar upward trend as the CDC findings, in reality, Ohio's drug overdose death rate is significantly higher than the national average. For example, in 2015, the national drug overdose death rate

[14] *See* GOVERNOR'S CABINET OPIATE ACTION TEAM, http://fightingopiateabuse.ohio.gov/, (last visited June 24, 2018); OHIO DEPARTMENT OF HEALTH, 2016 OHIO DRUG OVERDOSE DATA: GENERAL FINDINGS (2017), *available at* https://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2016-Ohio-Drug-Overdose-Report-FINAL.pdf?la=en.

[15] *Id.*

was 16.3 per 100,000. In Ohio, however, the drug overdose death rate was 29.9 per 100,000. By 2016, the Ohio drug-related overdose death rate increased over 30% to 39.1 per 100,000.[16]

26. MetroHealth has borne the brunt of the public health crisis from the skyrocketing opioid addiction and opioid-related overdoses, treatments, and deaths, both financially as well as in a forced diversion of resources, and continues to address this ongoing public health crisis. As the safety net hospital that cares for the public health needs of Cuyahoga County's most vulnerable populations, MetroHealth is on the front line of combating the public health crisis created by Defendants in Northeast Ohio.

27. The public health crisis is a continuing public nuisance that MetroHealth is obligated to attempt to abate because it constitutes unreasonable interference with, and injury to, the public health and safety of the residents in Cuyahoga County as a whole and more broadly in Northeast Ohio.

28. Similar to the State of Ohio, MetroHealth has been struck particularly hard by the increase in the number of opioid addicted individuals seeking care at its facilities as a direct result of the Marketing Defendants' unlawful activities.

29. So, too, have the fatalities increased. For example, in 2004, there 114 overdose deaths in the geographic area served by MetroHealth.[17] In 2016, there were 656 such deaths, constituting a 475% increase.[18] Available data for 2018 shows the upward trend of overdose fatalities continuing.

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[16] *See Drug Overdose Death Data*, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/drugoverdose/data/statedeaths.html (last updated Dec. 19, 2017).

[17] *See Drug Overdose in Ohio*, OHIO DEP'T OF HEALTH, https://www.odh.ohio.gov/health/vipp/drug/dpoison.aspx (last updated Nov. 14, 2017).

[18] *Id.*

30. The catastrophic effects of each Marketing Defendant's unlawful deceptive marketing scheme are only getting worse.

31. MetroHealth brings this lawsuit to enjoin the continuing violations of all the Defendants and to obtain damages for the enormous remedial effort it has been forced to expend to prevent opioid addiction, treat and attempt to rehabilitate the thousands of addicted individuals in its public health care service area, treat any related illness, purchase, supply, and instruct the surrounding community with overdose prevention kits, provide care to an increasing number of addicted mothers and children born with neonatal abstinence syndrome, and provide psychological care for the families of addicted individuals. Additionally, MetroHealth seeks to require the Defendants to fund the abatement of the public nuisance Defendants created by paying for the extensive remedial initiatives MetroHealth has put in place, and will continue to keep in place, to try to ameliorate the effects of the opioid epidemic in Cuyahoga County.

32. Defendants' conduct has violated, and continues to violate, the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §1961, *et seq.* ("RICO"). Additionally, Defendants' conduct constitutes a common law public nuisance, civil conspiracy, common law fraud, negligent misrepresentation, negligence, negligence *per se*, violation of Ohio Corrupt Practices Act, and unjust enrichment. Plaintiff does not allege that any product was defective and expressly does not bring product liability claims.

33. To redress and enjoin Defendants' previous and continuous violations of the law, Plaintiff brings this action seeking abatement, restitution, damages, treble damages, disgorgement of unlawful profits, civil penalties, and attorneys' fees and costs permitted by law and equity.

II. JURISDICTION AND VENUE

34. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1331 because Plaintiff's claims under RICO raise a federal question. This Court has supplemental jurisdiction over the Plaintiff's state-law claims under 28 U.S.C. §1367 because those claims are so related to the RICO claim as to form part of the same case or controversy.

35. This Court has personal jurisdiction over all Defendants under R.C. 2307.382 because the causes of action alleged in this Complaint arise out of each Defendant's transacting business in Ohio, contracting to supply services or goods in this state, causing tortious injury by an act or omission in this state, and because Defendants regularly do or solicit business, engage in a persistent course of conduct, or derive substantial revenue from goods sold in this State. Defendants have purposefully directed their action towards Ohio and/or have the requisite minimum contacts with Ohio to satisfy any statutory or constitutional requirements for personal jurisdiction.

36. Venue is proper in this District pursuant to 28 U.S.C. §1391(b)(2) in that a substantial part of the events or omissions giving rise to the claim occurred in the Northern District of Ohio. Venue is also proper under 18 U.S.C. §1965(a) because Defendants reside, are found, have agents, or transact their affairs in this District.

III. PARTIES

A. Plaintiff

37. Plaintiff MetroHealth is a public health system in Cleveland, Ohio servicing the residents of Cuyahoga County since 1837. It has more than 25 locations throughout Cuyahoga County. In 2017, MetroHealth served 300,000 patients at more than 1.4 million visits in its hospitals and health centers, 75 percent of whom are uninsured or covered by Medicare and Medicaid.

38. MetroHealth is a "county hospital" within the meaning of R.C. 339.01.

39. MetroHealth provides up to full financial assistance to Ohio residents who cannot afford to pay for their medical care.

40. MetroHealth is governed by a board of trustees.

41. MetroHealth owns facilities throughout Cuyahoga County and employs approximately 7,500 employees. MetroHealth bears a self-insured retention, followed by a captive insurance policy up to a $1 million, for its employees' medical and health insurance.

42. MetroHealth brings this action on its own behalf.

B. Defendants

1. Marketing Defendants

Purdue Defendants

43. Defendant Purdue Pharma L.P. ("PPL"), registered and doing business in Connecticut as Purdue Pharma (Delaware) Limited Partnership, is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

44. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut.

45. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

46. PPL, PPI, and PFC (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in MetroHealth, including the following:

Table 1 - Purdue Opioids

Drug Name	Chemical Name
OxyContin	Oxycodone hydrochloride extended release
MS Contin	Morphine sulfate extended release
Dilaudid	Hydromorphone hydrochloride
Dilaudid-HP	Hydromorphone hydrochloride
Butrans	Buprenorphine
Hysingla ER	Hydrocodone bitrate
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride

47. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $3.1 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers). Sales of OxyContin (launched in 1996) went from a mere $49 million in its first full year on the market to $1.6 billion in 2002.

48. In 2007, Purdue settled criminal and civil charges brought against it by the U.S. Department of Justice ("DOJ") for misbranding OxyContin and agreed to pay the United States over $600 million – at the time, one of the largest settlements with a drug company for marketing misconduct – as well as a sweeping set of injunctive relief requiring the Defendant to cease its unlawful and deceptive marketing practices. *See United States of America v. Purdue Frederick Co., Inc.*, No. 1:07CR00029, Plea Agreement (W.D. Va. May 10, 2007). The company admitted that its supervisors and employees, "with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications." *Id.* Simultaneously, Purdue settled an action brought by 27 state attorneys general for $20 million and further injunctive relief.

49. Upon information and belief, Purdue has violated most, if not all, of its commitments under its consent decrees with the Government.

Cephalon Defendants

50. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation.

51. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

52. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute, and sell both brand-name and generic versions of opioids nationally and in MetroHealth, including the following:

Table 2 - Cephalon Opioids

Drug Name	Chemical Name	Form
Actiq	Fentanyl citrate	Lollipop or lozenge
Fentora	Fentanyl	Buccal tablet, like a smokeless tobacco plug

53. In September 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA") for its misleading promotion of Actiq (and two other drugs) and agreed to pay $425 million in fines, damages, and penalties.

Janssen Defendants

54. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

55. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of J&J.

56. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), now known as Janssen Pharmaceuticals, is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

57. Janssen Pharmaceuticals was formerly known as OMP, which in turn was formerly known as Janssen Pharmaceutica, Inc.

58. Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), now known as Janssen Pharmaceuticals, is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

59. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals stock. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals's drugs and profits inure to J&J's benefit.

60. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica (collectively, "Janssen") are, or have been, engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in MetroHealth, including the following:

Table 3 - Janssen Opioids

Drug Name	Chemical Name	Form
Duragesic	Fentanyl	Transdermal Patch
Nucynta (prior to 2015)	Tapentadol hydrochloride	Tablet
Nucynta ER (prior to 2015)	Tapentadol hydrochloride	Extended release tablet

61. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least $1 billion in annual sales.

Endo Defendants

62. Defendant Endo Health Solutions Inc. ("EHS") is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

63. Defendant Endo Pharmaceuticals, Inc. ("EPI") is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

64. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are collectively referred to as "Par Pharmaceutical." Par Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating company of Endo International plc.

65. EHS, EPI, and Par Pharmaceutical (collectively, "Endo") manufacture, promote, distribute, and sell opioids nationally and in MetroHealth, including the following:

Table 4 - Endo Opioids

Drug Name	Chemical Name	Form
Opana ER	Oxymorphone hydrochloride	Extended release tablet
Opana	Oxymorphone hydrochloride	Tablet
Percodan	Oxycodone hydrochloride and aspirin	Tablet
Percocet	Oxycodone hydrochloride and acetaminophen	Tablet

66. Opioids comprised approximately $403 million of Endo's overall revenue of $3 billion in 2012. Opana ER yielded revenue of $1.15 billion from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc. ("Qualitest"), including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

67. A reformulated Opana ER that had been approved in 2012 was removed from the market in June 2017 at the request of the FDA, which found that "the benefits of the drug may no longer outweigh its risks."[19] The FDA stated it had "determined that the data did not show that the reformulation could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for Opana ER."[20]

Actavis Defendants

68. Allergan Finance, LLC ("Allergan") is a privately held Nevada corporation with its principal place of business in Parsippany, New Jersey. Allergan was formerly known as Actavis, Inc., which in turn was formerly known as Watson Pharmaceuticals, Inc. Allergan is an indirect wholly owned subsidiary of Allergan plc, which is incorporated in Ireland with its principal place of business in Dublin, Ireland. Allergan and its predecessors, affiliates, and/or combining entities, including, but not limited to, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., and Watson Laboratories, Inc., are referred to collectively herein as "Actavis."

69. Actavis manufactures, promotes, sells, and distributes opioids nationally and in MetroHealth, including the following opioids, as well as their generic versions:

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[19] News release, FDA, FDA requests removal of Opana ER for risks related to abuse (June 8, 2017) (available at https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm562401.htm).

[20] *Id.*

Table 5 - Actavis Opioids

Drug Name	Chemical Name	Form
Kadian	Morphine sulfate	Extended release tablet
Norco	Hydrocodone bitartrate and acetaminophen	Tablet

70. Kadian is an extended-release tablet for "the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. and began marketing Kadian in 2009.

Defendant Mallinckrodt

71. Since 2013, Mallinckrodt LLC is a wholly owned subsidiary of Mallinckrodt PLC. It is a limited liability company organized and existing under the laws of the State of Delaware with its headquarters in St. Louis, Missouri. Prior to 2013, it was a wholly owned subsidiary of Irish public limited company Covidien PLLC (formerly known as Tyco Healthcare).

72. Mallinckrodt manufactures, promotes, sells, and distributes opioids nationally and in MetroHealth, including the following opioids, as well as their generic versions:

Table 6 - Mallinckrodt Opioids

Drug Name	Chemical Name	Form
Exalgo	Hydromorphone hydrochloride	Extended release tablet
Xartemis XR	Oxycodone hydrochloride and acetaminophen	Extended release tablet
Roxicodone	Oxycodone hydrochloride	Tablet
Methadose	Methadone hydrochloride	Tablet

73. Mallinckrodt also manufactures, markets, and sells generic oxycodone, of which it is one of the largest manufacturers.

74. In July 2017, Mallinckrodt agreed to pay $35 million to settle allegations brought by the DOJ that it failed to detect and notify the U.S. Drug Enforcement Administration ("DEA") of suspicious orders of controlled substances.

Defendant Insys

75. Defendant Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona.

76. Since 2012, Insys has been manufacturing and selling the following opioid:

Table 7 - Insys Opioid

Drug Name	Chemical Name	Form
Subsys	Fentanyl	Sublingual spray absorbed through mucous in the mouth

77. Subsys is a highly addictive synthetic opioid mouth spray approved for treatment of cancer pain in patients who are tolerant of other opioids. Subsys is a form of fentanyl – a narcotic up to 50 times more powerful than heroin and 100 times more powerful than morphine.

78. According to Insys's 2016 Annual Report, Subsys was the most prescribed transmucosal immediate-release fentanyl, with 42% market share, which translates to nearly $300 million in annual U.S. product sales for Insys – an increase of 270% in sales over just a year. *See* Insys Therapeutics, Inc., Annual Report at 1 (Form 10-K)(Apr. 3, 2017).

79. The broad sales of Subsys raised suspicions over Insys's sales practices, especially because it appeared that only 1% of Subsys sales were generated by oncologists, and the only approved use of Subsys is for a subset of cancer patients. Subsequent investigations revealed that Insys executives (including Individual Defendant Kapoor, named below) devised and sanctioned blatantly unlawful methods to increase sales for off-label uses to the profound harm, including death, of many patients.

80. On December 6, 2016, six former Insys executives were indicted by the U.S. Attorney for the District of Massachusetts for their participation in an alleged "nationwide conspiracy" to give healthcare providers kickbacks in exchange for the improper prescribing of Subsys. On October 24, 2017, a superseding indictment named and incorporated Individual Defendant Kapoor for his role in Insys's alleged "nationwide conspiracy."[21]

81. A Senate investigation into the opioid crisis generally began with an investigation into Insys, specifically. The conclusion to the initial report, *Fueling an Epidemic*, states that Insys "has repeatedly employed aggressive and likely illegal techniques to boost prescriptions for its fentanyl product Subsys . . . [that] included actions to undermine critical safeguards in the prior authorization process[.]"[22] The Senate investigation confirmed anecdotal evidence that sales representatives were instructed to encourage their sales "targets" (the physician, physician's assistant, nurse practitioner, or staff of the medical group with whom they met) to start the patient on a higher dosage of Subsys than was approved by the FDA. The sales representatives were told to explain to the physician that the reason to start the patient at a higher dose was to improve the pain relief outcome to the patient, but the true reason was to increase Insys's revenue. There is anecdotal evidence that the "motto" among the sales force in many regions of the country, including Ohio, was "start them high and hope they don't die."

82. The Defendants named above in ¶¶43-46, 50-52, 54-60, 62-65, 68, 71, 75 are collectively referred to herein as the "Marketing Defendants."

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[21] *United States v. Michael Babich, Alec Burlakoff, Richard Simon, Sunrise Lee, Joseph Rowan, and Michael Gurry, John Kapoor*, U.S. DEP'T JUST., https://www.justice.gov/usao-ma/victim-and-witness-assistance-program/united-states-v-michael-babich-alec-burlakoff-richard-simon-sunrise-lee-joseph-rowan-and (last updated Apr. 4, 2018).

[22] U.S. CONG. S. COMM. ON HOMELAND SEC. AND GOV'T. AFFAIRS, FUELING AN EPIDEMIC: INSYS THERAPEUTICS AND THE SYSTEMIC MANIPULATION OF PRIOR AUTHORIZATION (Sept. 6, 2017), *available at* https://www.hsdl.org/?view&did=803959.

83. For ease of reference, the following is a table of all Marketing Defendants and their principal opioid products:

Table 8

Purdue Opioids	
Drug Name	**Chemical Name**
OxyContin	Oxycodone hydrochloride extended release
MS Contin	Morphine sulfate extended release
Dilaudid	Hydromorphone hydrochloride
Dilaudid-HP	Hydromorphone hydrochloride
Butrans	Buprenorphine
Hysingla ER	Hydrocodone bitrate
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride

Table 8

Cephalon Opioids		
Drug Name	**Chemical Name**	**Form**
Actiq	Fentanyl citrate	Lollipop or lozenge
Fentora	Fentanyl	Buccal tablet, like a smokeless tobacco plug
Janssen Opioids		
Drug Name	**Chemical Name**	**Form**
Duragesic	Fentanyl	Transdermal Patch
Nucynta (prior to 2015)	Tapentadol hydrochloride	Tablet
Nucynta ER (prior to 2015)	Tapentadol hydrochloride	Extended release tablet
Endo Opioids		
Drug Name	**Chemical Name**	**Form**
Opana ER	Oxymorphone hydrochloride	Extended release tablet
Opana	Oxymorphone hydrochloride	Tablet
Percodan	Oxymorphone hydrochloride and aspirin	Tablet
Percocet	Oxymorphone hydrochloride and acetaminophen	Tablet

Actavis Opioids		
Drug Name	**Chemical Name**	**Form**
Kadian	Morphine sulfate	Extended release tablet
Norco	Hydrocodone bitartrate and acetaminophen	Tablet
Mallinckrodt Opioids		
Drug Name	**Chemical Name**	**Form**
Exalgo	Hydromorphone hydrochloride	Extended release tablet
Xartemis XR	Oxycodone hydrochloride and acetaminophen	Extended release tablet
Roxicodone	Oxycodone hydrochloride	Tablet
Methadose	Methadone hydrochloride	Tablet
Insys Opioid		
Drug Name	**Chemical Name**	**Form**
Subsys	Fentanyl	Sublingual spray absorbed through mucous membranes in the mouth

2. Individual Defendants

84. Defendant Kapoor is the founder, former Chairman of the Board, and Chief Executive Officer ("CEO") of Marketing Defendant Insys. He remains the majority stockholder of the company. Defendant Kapoor was indicted in Boston, Massachusetts, federal court on October 24, 2017 on charges of conspiracies to commit racketeering pursuant to 18 U.S.C. §1962(d), mail fraud pursuant to 18 U.S.C. §1349, wire fraud pursuant to 18 U.S.C. §1349, and violation of the Anti-Kickback Law pursuant to 18 U.S.C. §371. The indictment arose from the practice of Insys, which, upon information and belief, was devised by Defendant Kapoor, along with some other Insys executives, of paying kickbacks to doctors to write large numbers of prescriptions. Upon information and belief, Defendant Kapoor is a citizen of the State of Arizona.

85. Defendant Richard Sackler has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon information and belief, Defendant Richard Sackler resides in the State of Connecticut.

86. Defendant Jonathan Sackler has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon information and belief, Defendant Jonathan Sackler resides in the State of Connecticut.

87. Defendant Mortimer D.A. Sackler has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon information and belief, Defendant Mortimer D.A. Sackler resides in the State of New York.

88. Defendant Kathe Sackler has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon information and belief, Defendant Kathe Sackler resides in the State of Connecticut.

89. Defendant Ilene Sackler Lefcourt has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon information and belief, Defendant Ilene Sackler Lefcourt resides in the State of New York.

90. Defendant Beverly Sackler has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon information and belief, Defendant Beverly Sackler resides in the State of Connecticut.

91. Defendant Theresa Sackler has been a member of the board of Purdue Pharma Inc. since the 1990s. Upon Information and belief, Defendant Theresa Sackler resides in the United Kingdom.

92. David Sackler has been a member of the board of Purdue Pharma Inc. since the 2012. Upon information and belief, Defendant David Sackler resides in the State of New York.

93. Defendants Richard Sackler, Jonathan Sackler, Mortimer D.A. Sackler, Kathe Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, and David Sackler are collectively referred to herein as the "Sackler Family Defendants."

94. The Marketing Defendants and Individual Defendants are collectively referred to herein as the "Defendants."

IV. FACTUAL ALLEGATIONS

A. The Scientific Basis for Pain-Relieving and Addictive Properties of Opioids

1. Similarity Between Prescription Opioids and Heroin

95. The medicinal effects of opium, an extract from the flowering poppy plant that relieves pain and often causes euphoria, have been known for thousands of years.

96. In the early 1800s, a German pharmacist, Freidrich Sertürner, isolated a molecule from opium and named it "morphine" for its hypnotic, as well as analgesic, properties.

97. The late 1800s and early 1900s saw a plethora of semi-synthetic opioids that were easily derived by manipulating the basic morphine structure. Semi-synthetic opioids produce a more rapid effect than morphine because they cross the blood-brain barrier more easily.

98. One of the first semi-synthetic opioids, heroin, began being manufactured in the late 19th century. In 1914, the Harrison Narcotics Tax Act imposed a tax on those making, importing, or selling any derivative of opium. By the 1920s, physicians were aware of the highly addictive nature of opioids and tried to avoid treating patients with them. Heroin became illegal in 1924.

99. Other semi-synthetic opioids, such as oxycodone, hydrocodone, oxymorphone, and hydromorphone, continued to be designed in laboratories and approved for restricted medical uses. All the opioids sold by Marketing Defendants Purdue, Endo, Actavis, and Mallinckrodt fall within these categories. *See supra* Table 8, ¶83.

100. In 1960, a fully synthetic opioid, named fentanyl, was synthesized by Dr. Paul Janssen in Belgium.

101. Fentanyl has been produced in various forms, including lollipops (Actiq) and a spray absorbed through the mouth (Subsys). The products of Marketing Defendants Cephalon, Janssen, and Insys (listed *supra* in Table 8, ¶83) are fentanyl or fentanyl-based synthetic opioids.

102. All these opioids, comprised of semi-synthetic and fully synthetic opioids, work on a patient in very similar ways. They react with opioid receptors in the brain of the patient and are considered "full agonists." "Agonists interact with a receptor to produce a maximal response from that receptor."[23]

103. When a full agonist opioid interacts with the opioid receptor, there is a cascade of reactions, ultimately leading to an increase in the release of dopamine in the brain.[24]

104. Opiate receptor stimulation by opioids can relieve pain and produce euphoria. These effects have been understood for millennia as properties of opium.

105. However, a known result of the physiological process for all opioids (just as it has been for millennia with the opium from the poppy plant) is that tolerance and dependence develop rapidly if the opioids are taken on a daily basis.

106. Tolerance results in the need to take higher doses to achieve the same effect.

107. Dependence results in dysphoria, increased pain sensitivity, anxiety, insomnia, pain, blurry vision, rapid heartbeat, chills, panic attacks, nausea, vomiting, and tremors when opioids are discontinued. These symptoms lead to cravings to continue use.

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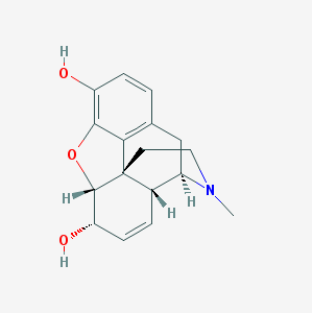
[23] Hasan Pathan & John Williams, *Basic Opioid Pharmacology: An Update*, 6 BRIT. J. PAIN 11 (2012).

[24] Nora D. Volkow, M.D., et al., *Neurobiologic Advances from the Brain Disease Model of Addiction*, 374 NEW ENG. J. MED. 363 (2016), *available at* http://www.nejm.org/doi/full/10.1056/NEJMra1511480#t=article.

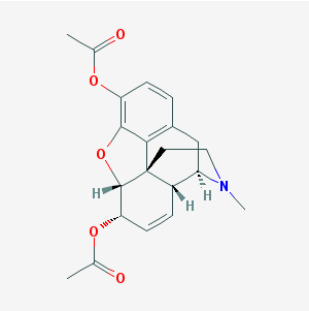
108. Dependence on dangerous narcotics, such as opioids, particularly among elderly patients, also creates a greater risk of respiratory depression, causing addicted individuals to stop breathing and die from suffocation.

109. Commonly prescribed opioids produce effects that are indistinguishable from the effects produced by other semi-synthetic opioids. As the following charts demonstrate, the molecular composition of morphine, heroin, and the synthetic derivatives therefrom, which are the opioid prescriptions being sold by Marketing Defendants, are virtually identical.

Morphine[25]

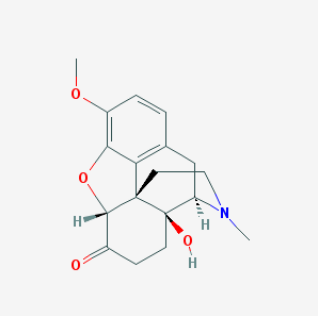


Heroin[26]



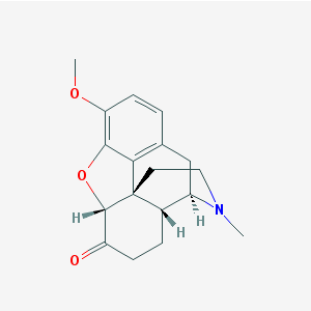
Oxycodone[27]

(sold as Percocet, OxyContin)



Hydrocodone[28]

(sold as Vicodin)



[25] Sunghwan Kim, et al., *Compound Summary for CID 5288826: Morphine*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/5288826 (last updated June 23, 2018).

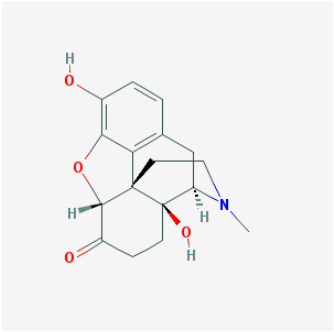
[26] Sunghwan Kim, et al., *Compound Summary for CID 5462328: Diamorphine*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/5462328 (last updated June 23, 2018).

[27] Sunghwan Kim, et al., *Compound Summary for CID 5284603: Oxycodone*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/5284603 (last updated June 23, 2018).

[28] Sunghwan Kim, et al., *Compound Summary for CID 5284569: Hydrocodone*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/5284569 (last updated June 23, 2018).

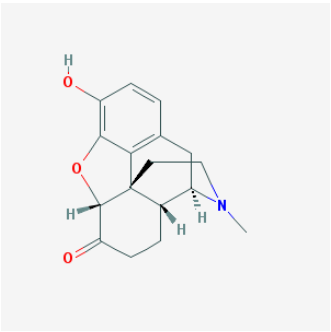
Oxymorphone[29]

(sold as Opana)



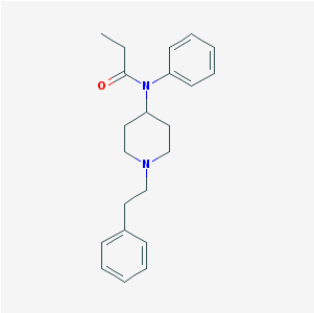
Hydromorphone[30]

(sold as Dilaudid)



Fentanyl[31]

(sold as Subsys)



110. It is simple to see from these charts how chemically similar the natural morphine, heroin, and semi-synthetic opioids are to one another. The opioid pain relievers ("OPRs") all share the same five-ring structure that allows them to react with opioid receptors in the brain.

[29] Sunghwan Kim, et al., *Compound Summary for CID 5284604: Oxymorphone*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/5284604 (last updated June 23, 2018).

[30] Sunghwan Kim, et al., *Compound Summary for CID 5284570: Hydromorphone*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/5284570 (last updated June 23, 2018).

[31] Sunghwan Kim, et al., *Compound Summary for CID 3345: Fentanyl*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., https://pubchem.ncbi.nlm.nih.gov/compound/3345 (last updated June 23, 2018).

While fentanyl and other synthetic opioids do not share the same five-ring structure, they nevertheless interact with opioid receptors in the brain the same way.

111. Dr. Andrew Kolodny, Senior Scientist and Co-Director of Opioid Policy Research at the Heller School for Social Policy and Management and co-founder of Physicians for Responsible Opioid Prescribing, called prescription opioids "heroin pills":[32]

> Like heroin, most OPRs are made from opium. Their molecular structure is nearly identical to that of heroin and the effects they produce in the brain are indistinguishable from heroin. What this means is that when we talk about OPRs, we are essentially talking about "heroin pills."

112. Commonly prescribed opioid analgesics have the same pain-relieving, euphoria-inducing, intensely addictive qualities of morphine and heroin.

113. A Columbia University study found that experienced heroin users preferred the effects of oxycodone over the effects of heroin.[33]

2. Biology of Why a Person with a Prescription Opioid Addiction Frequently Turns to Street Drugs

114. With daily use of opioids, in as little as one week, patients can experience withdrawal symptoms if opioids are discontinued (commonly referred to as "dependence"). Once dependent, cessation of use produces deeply unpleasant symptoms such as dysphoria, increased pain sensitivity, anxiety, insomnia, pain, blurry vision, rapid heartbeat, chills, panic attacks, nausea, vomiting, and tremors.

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[32] *America's Addiction to Opioids: Heroin and Prescription Drug Abuse: Hearing Before the U.S. S. Caucus on Int'l. Narcotics Control*, 113th Cong. 2 (2014) (statement of Andrew Kolodny, M.D., Chief Medical Officer, Phoenix House Foundation), at 2, *available at* https://www.drugcaucus.senate.gov/content/senate-caucus-international-narcotics-control-hearing-america%E2%80%99s-addiction-opioids-heroin-and.

[33] Sandra D. Comer, Ph.D., et al., *Abuse Liability of Prescription Opioids Compared to Heroin in Morphine-Maintained Heroin Abusers*, 33 NEUROPSYCHOPHARMACOLOGY 1179 (June 20, 2007), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3787689.

115. Dr. Kolodny has explained the effect of opioids as akin to "hijack[ing] the brain's reward system," which in turn convinces a user that "the drug is needed to stay alive."[34]

116. When under the continuous influence of opioids over a period of time, patients grow tolerant to the analgesic or pain-relieving effects. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same levels of pain reduction he or she has become accustomed to – up to and including doses that are considered to be "frighteningly high."[35] At higher doses, the effects of withdrawal are more substantial and risk of addiction increases. The FDA has acknowledged that available data suggests a relationship between increased doses and the risk of adverse effects.[36]

117. As addiction science shows, once an individual is addicted to any of these products, a series of biochemical reactions and physiological changes in the brain make it very difficult to break the addiction, even if the patient desperately wants to do so. These known brain changes in addicted persons also explain why addiction is a relapsing disease.

118. As the New England Journal of Medicine explains:

> This attenuated release of dopamine renders the brain's reward system much less sensitive to stimulation by both drug-related and non-drug-related rewards. As a result, persons with addiction no longer experience the same degree of euphoria from a drug as they did when they first started using it. It is for this same reason that persons with addiction often become less motivated by everyday stimuli (e.g., relationships and activities) that they had previously found to be motivating and rewarding. Again, it is important to note that these changes become deeply

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[34] David Montero, *Actor's death sows doubt among O.C.'s recovering opioid addicts*, THE ORANGE CNTY. REGISTER (Feb. 4, 2014), https://www.ocregister.com/2014/02/04/actors-death-sows-doubt-among-ocs-recovering-opioid-addicts/.

[35] Mitchell H. Katz, M.D., *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170 ARCHIVES OF INTERNAL MED. 1422 (2010), available at https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/225880?redirect=true.

[36] Volkow, *supra* n.4.

> ingrained and cannot be immediately reversed through the simple termination of drug use (e.g., detoxification).[37]

119. As addiction deepens, the changes in the brain of the addict become more profound. The deadened mood affect and pre-occupation with continued use to the exclusion of previously pleasurable activities are aggravated by a lessened ability to control impulses. Further:

> [t]he changes that occur in the reward and emotional circuits of the brain are accompanied by changes in the function of the prefrontal cortical regions, which are involved in executive processes. Specifically the down-regulation of dopamine signaling that dulls the reward circuits' sensitivity to pleasure also occurs in prefrontal brain regions and their associated circuits, seriously impairing executive processes, among which are the capacities for self-regulation, decision making, flexibility in the selection and initiation of action, attribution of salience (the assignment of relative value), and the monitoring of error.[38]

120. Recent research on the brains of addicted individuals makes clear why that person would substitute heroin or fentanyl for prescription opioids, and further, why the changes in the individual's brain caused by the addiction to prescription opioids makes it almost impossible to resist the need for continued use, even to the point of death.

121. In short, the progression of addiction is, first, the initial pain relief and feeling of well-being or euphoria experienced by the patient. Next is the craving for more and more of the substance, since the dopamine rewards system has been hijacked and the patient is incapable of experiencing everyday joys. Even greater and more frequent amounts of the opioid do not work, since the patient's dopamine reward system is broken. As addiction proceeds, the patient becomes increasingly incapable of thinking through the situation, since his or her prefrontal cortical regions have become affected. Therefore, a person who has become addicted to opioids

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37 *Id.*

38 *Id.*

feels compelled to continue using and will switch to heroin or fentanyl if it is easier and less expensive to obtain.

3. Biology of Why a Person with an Opioid Addiction Frequently Turns to Crime[39]

122. Opioid addiction is different from other chronic diseases. The opioid-addicted individual will behave in ways that appear anti-social. Even a threat of severe punishment is insufficient to keep them from continuing their opioid use. They will give up everything and everyone they have ever cared about to maintain their opioid supply. The anti-social behavior that opioid-addicted individuals engage in is not driven by character flaws or moral failing. Instead, the behavior is secondary to the development of addiction. Once addicted, good people will behave in ways they never could have imagined.

123. When a pregnant woman uses opioids, it does not just affect her. It affects her unborn child. Some of the primary effects of opioid use during a pregnancy can include problems with the placenta, an increased risk of preterm birth, and low birth weight. The placenta is an essential component of a healthy pregnancy because it is responsible for delivering blood to the baby through the umbilical cord. When there is a problem with the placenta, it can cause the baby to be deprived of oxygen or nutrients. Opioid use during a pregnancy can also cause the placenta to separate from the uterus in a severe condition call placental abruption, low birth weight (which is commonly associated with chronic disease and issues with cognitive development throughout a child's life), Neonatal Abstinence Syndrome ("NAS"), stillbirth, and an increased risk of sudden infant death syndrome.

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[39] Nora D. Volkow, et al., *Addiction: Decreased Reward Sensitivity and Increased Expectation Sensitivity Conspire to Overwhelm the Brain's Control Circuit*, 32 BIOESSAYS 748 (2010).

124. In addition to these short-term effects on babies born to opioid-addicted mothers, there may also be lasting long-term effects as well. Studies on the long-term effects of drug use on a fetus have shown that that toddlers exposed to drugs in the womb had problems with, among other things, behavior control.

B. Lack of Evidence that Long-Term Opioid Use Was a Valid Pain Treatment

125. Marketing Defendants have always been aware that there was no real evidence of the safety and efficacy of opioids for long-term use. To the contrary, there was evidence that, with long-term use, opioid drugs would become less effective because of tolerance to the pain relieving effects.

126. A 2006 efficacy study found that opioids as a class did not demonstrate improvement in "function" over other non-addicting treatments. It stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids.[40]

127. Endo's own research shows that patients taking opioids, as opposed to other prescription pain medicines, report higher rates of obesity (30-39%), insomnia (9-22%), and self-described fair or poor health (24-34%).

128. In the fall of 2009, as a pain specialist noted in an article, *Are we making pain patients worse?*, "[O]pioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over

[40] Andrea D. Furlan, et al., Opioids for Chronic Noncancer Pain: A Meta-Analysis of Effectiveness and Side Effects, 174 CAN. MED. ASS'N J. 1589 (2006). This same study revealed that efficacy studies do not typically include data on opioid addiction. In many cases, patients who may be more prone to addiction are pre-screened out of the study pool. This does not reflect how doctors actually prescribe the drugs, because even patients who have past or active substance use disorders tend to receive higher doses of opioids. *See* Karen H. Seal, M.D., et al., *Association of Mental Health Disorders With Prescription Opioids and High-Risk Opioid Use in US Veterans of Iraq and Afghanistan*, 307 J. AM. MED. ASS'N 940 (2012).

time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[41]

129. Workers' compensation data has also long revealed the lack of evidence for the efficacy of opioids for long-term chronic pain. Claims involving workers who take opioids are almost four times as likely to reach costs of over $100,000 than claims without opioids, as these patients suffer greater side effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, receiving an opioid for more than seven days and receiving more than one opioid prescription increased the risk that the patient would be on work disability one year later. A prescription for opioids as the first treatment for a workplace injury doubled the average length of the claim.

130. Undaunted by this body of evidence questioning the efficacy and safety of opioids, the Marketing Defendants mounted their disinformation campaign to expand the market for their drugs, despite the risk of addiction.

C. Campaign of Misinformation and Unlawful Conduct by Marketing Defendants

1. Summary of Marketing Defendants' Disinformation Campaign

131. Marketing Defendants, through a sophisticated and highly deceptive and unfair marketing campaign that began in the mid-to-late 1990s and continues to the present, set out to and succeeded in reversing the popular and medical understanding of opioids. Chronic opioid therapy – the prescribing of opioids to treat chronic pain long-term – is now a commonplace and highly dangerous practice in the United States.

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[41] Andrea Rubenstein, M.D., *Are We Making Pain Patients Worse?*, SONOMA MED. (Fall 2009), http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse.aspx?pageid=144&tabid=747.

132. MetroHealth is on the forefront of reversing this dangerous practice and is currently engaging in numerous initiatives (*see infra* ¶¶354, 389-390, 398-415, 426-434) to reduce the number of opioid prescriptions in circulation and treat its increasingly drug-addicted patient population.

133. Since Insys did not begin selling its fentanyl-based product, Subsys, until 2012, they did not participate in the activity preceding that date. Nevertheless, Insys did profit from the collusive campaign of other Marketing Defendants to change medical orthodoxy solely for reasons of greed rather than a scientific basis and continues to misrepresent the safety and efficacy of opioid treatment for chronic pain. Moreover, Insys engaged in outrageously fraudulent practices to sell its drug, Subsys, resulting in indictments of six of its executives, including Individual Defendant Kapoor, and untold deaths and devastation to Americans, including the patient population of Cuyahoga County.

134. To accomplish this reversal, Marketing Defendants spent hundreds of millions of dollars: (a) developing and disseminating seemingly truthful scientific and educational materials and advertising that misrepresented the risks, benefits, and superiority of opioids for treating chronic pain; (b) funding, assisting, encouraging, and directing KOLs to deliver scripted talks, publish misleading studies, and present CMEs that disseminated false and incomplete information to medical practitioners; (c) infiltrating the boards and committees of professional societies and patient advocacy groups that delivered messages and developed guidelines supporting chronic opioid therapy; (d) funding, assisting, directing, and encouraging seemingly neutral and credible Front Groups that developed misleading educational materials and treatment guidelines that were subsequently distributed, urging doctors to prescribe, and patients to use, opioids long-term to treat chronic pain; (e) deploying sales representatives who visited doctors

and other prescribers who marketed their opioids for "non-indicated" or off-label purposes, not approved by the FDA, thereby violating 21 U.S.C. §§331(a)-(b), 352(a), and further understated the risk of addiction; and (f) targeting public ads to vulnerable populations, such as the elderly and veterans.

135. Marketing Defendants: (a) overstated the benefits of chronic opioid therapy, promised improvement in patients' function and quality of life, and failed to disclose the lack of evidence supporting long-term use; (b) trivialized or obscured opioids' serious risks and adverse outcomes, including the risks of addiction, overdose, and death; (c) overstated their superiority compared with other treatments, such as other, non-opioid analgesics, physical therapy, and other alternatives; and (d) mischaracterized the difficulty of withdrawal from opioids and the prevalence of withdrawal symptoms. There is not, and there never has been, reliable scientific evidence to support Marketing Defendants' marketing claims. There has long been, and there continues to be, substantial scientific evidence that these claims are false.

2. False Messaging

a. Drug Companies Must Deal Honestly with Patients, Consumers, and Governmental Payors

136. Like every other business in Ohio, pharmaceutical Marketing Defendants have a duty to deal honestly and truthfully with consumers and to refrain from using unfair and deceptive acts to boost profits at the consumers' expense.

137. A drug company's representations about its drug must: (a) be consistent with its label and supported by substantial scientific evidence; (b) not include false or misleading statements or material omissions; and (c) fairly balance the drug's benefits and risks.

138. Furthermore, drug companies are not permitted to sell any drugs that are "misbranded," which means, among other things, that the "label" cannot be false or misleading.

"Labeling" includes more than the drug's physical label; it also includes "all . . . other written, printed, or graphic matter . . . accompanying" the drug, including promotional material.[42] The term "accompanying" includes promotional materials – posters, websites, brochures, books, etc. that are disseminated by or on behalf of the manufacturer of the drug.[43] Thus, Marketing Defendants' promotional materials are part of their drugs' labels and required to be accurate, balanced, and not misleading.

139. Labeling is misleading if it is not based on substantial evidence, materially misrepresents the benefits of a drug, or omits material information about or minimizes the frequency or severity of a product's risks. Promotion that fails to present the most important risks of a drug as prominently as its benefits lacks fair balance and is therefore deceptive.

140. Drug companies are also prohibited from distributing evidence or information about a drug's safety or efficacy, or presenting conclusions that "clearly cannot be supported by the results of the study."[44] Drug companies further must not make comparisons between their drugs and other drugs that represent or suggest that "a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience."[45]

141. Marketing Defendants long maintained that prescription opioids carry little to no risk of addiction, when they knew that not to be true. For example, Purdue claimed that the risk of addiction was negligible, even though its own studies had shown that between 8-13% of OxyContin patients became addicted.

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42 21 U.S.C. §321(m).

43 *See* Annotation, *Notes of Decisions: Accompanying the Article, Labeling,* 21 U.S.C.A. §321 (West).

44 21 C.F.R. §99.101(a)(4).

45 21 C.F.R. §202.1(e)(6)(ii).

142. Marketing Defendants have said that specific characteristics of their drugs made them less addictive, when there was no evidence to support their assertions. For example, Endo marketed Opana ER as being crush-resistant, and as a result, hard to abuse and harder to become addicted to. In fact, Endo knew that there was no evidence to support this assertion. Sales representatives for Purdue, Janssen, Endo, and Actavis promoted their drugs as having "steady-state" properties with the intent and expectation that prescribers would understand this to mean that their drugs caused less of a rush or a feeling of euphoria, which can trigger misuse and addictions.

143. Cephalon-sponsored *Treatment Options: A Guide for People Living with Pain* (American Pain Foundation, 2007) stated that addiction is limited to extreme cases of unauthorized dose escalations, getting opioids from multiple sources, or theft. In truth, Cephalon knew there was no basis for this depiction that addiction occurred only in rare cases.

144. Marketing Defendants have maintained that addiction risk can be managed by the prescribing physician by asking patients to fill out a questionnaire to assess their risk of addiction (known as "screening"). Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction. However, there is not, and there never has been, evidence to suggest that such screening is reliable.

145. Marketing Defendants falsely suggested or even blatantly proclaimed that withdrawal from opioids was not a problem. Actavis trained its sales force to assert that discontinuing opioid therapy can be handled "simply" and done at home, with the withdrawal period taking approximately a week, even in addicted patients. Janssen training materials between 2009 and 2011 repeatedly proclaimed "low incidence of withdrawal symptoms" as a "core message" for their sales force. In addition to claiming a low rate of withdrawal symptoms,

Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use. Janssen knew, or should have known, that these symptoms peak earlier than that for most patients.

146. Contrary to Marketing Defendants' assertions, opioids have been found time and time again to be addictive. A patient's fear of the unpleasant effects of discontinuing opioids, combined with the negative reinforcement during a period of actual withdrawal, can push a patient to seek further opioid treatment – even where ineffective or detrimental to quality of life – simply to avoid the deeply unpleasant effects of withdrawal.

b. Falsehood: No Upper Limit on the Amount of Opioids to a Consumer

147. Marketing Defendants have misrepresented and even denied entirely the dangers posed by large doses of opioids. Marketing Defendants claimed that dosages could be escalated continuously to match high pain tolerance, even though studies showed that such escalation could be deadly. This false advice has been disseminated even though the Marketing Defendants, their executives, researchers, and sales staff have knowledge that increasing a dosage or starting a patient with a high dosage may be fatal. *See supra* ¶¶81, 128; *infra* ¶150.

148. This falsehood is of particular concern because none of the Marketing Defendants' opioids have a cap on dosage.

149. There is not now, and there never has been, any scientifically based support for the Marketing Defendants' statements that there are no upper limits for opioids.

150. High doses pose real risk. The 2016 CDC Guidelines state, in pertinent part: "[b]enefits of high-dose opioids for chronic pain are not established," while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." They further state that there are "increased risks for opioid use disorder, respiratory depression, and death at higher

dosages[.]" As a result, the CDC now advises doctors to "avoid increasing dosage" above 90 morphine milligram equivalents ("MME") per day.

151. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he or she has become accustomed – up to and including doses that are "frighteningly high."[46] *Supra* ¶116. At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at continuously escalating dosages to match pain tolerance and still overdose at recommended levels.

c. Falsehood: Opioids Are the Best Solution

152. Marketing Defendants have consistently exaggerated the benefits and downplayed the side effects of opioids as compared to other analgesics. Specifically, Marketing Defendants have ignored the effects of long-term opioid therapy, which include addiction, hyperalgesia, hormonal dysfunction, decline in immune function, increased bone fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interaction with other medication taken to treat disorders frequently co-existing with chronic pain. At the same time, Marketing Defendants have greatly exaggerated the incidence of side-effects and the risk of death from medicines, such as aspirin or ibuprofen, technically known as non-steroidal anti-inflammatory drugs ("NSAIDs"). Marketing Defendants have suggested 16,000 annual deaths are attributable to NSAID induced gastrointestinal bleeding, when the real number is approximately 3,400 and shrinking.[47]

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[46] Katz, *supra* n.35.

[47] *See* John Fauber, *NSAID Bleeding Risk: Smoke But No Fire*, MILWAUKEE JOURNAL SENTINAL (May 30, 2012), https://www.medpagetoday.com/geriatrics/painmanagement/32971;

153. On the contrary, there is evidence that opioid drugs are less effective at treating chronic pain and may worsen patients' health. As noted, a comprehensive study in 2006 found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. Rather, the study concluded: "[f]or functional outcomes, the other analgesics were significantly more effective than were opioids."[48] The above study and similar ones that were antithetical to the position of the Marketing Defendants were simply not presented by the KOLs in their speeches to practitioners, in the lectures presented at CMEs controlled by the Marketing Defendants, or in the Front Groups used to disseminate the Marketing Defendants' false message that opioids are a superior pain treatment.

154. The Marketing Defendants knew, or reasonably should have known, their disparagement of NSAIDs and other analgesics was unfounded. Indeed, Endo's own internal research shows that patients taking opioid-based pain medicines specifically reported higher rates of obesity, insomnia, and self-described fair or poor health.

d. Falsehood: The Promise of a Pain-Free Life and Vigorous Existence

155. Marketing Defendants misrepresented that opioids improve functioning over time. For example, Janssen sponsored a patient education guide in 2009, *Finding Relief: Pain Management for Older Adults*, which states, as a fact, that "opioids may make it easier for people to live normally."

156. There is not, and there never has been, any data to support the claim that they do so; in fact, there is data to suggest that long-term opioid usage reduces functioning. Data from

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see also Courtney Krueger, PharmD, BCPS, *Ask the Expert: Do NSAIDs Cause More Deaths Than Opioids?*, PRACTICAL PAIN MGMT. (Nov./Dec. 2013), https://www.practicalpainmanagement.com/treatments/pharmacological/opioids/ask-expert-do-nsaids-cause-more-deaths-opioids.

[48] Furlan, *supra* n.40.

workers' compensation claims indicates that there is a negative correlation between opioid prescriptions and a person returning to work.[49]

157. The 2016 CDC Guidelines (*supra* ¶16) state that "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy." The CDC further found that "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

e. Falsehood: Tapering Is an Effective Way to Manage Any Withdrawal

158. Marketing Defendants also falsely represent that withdrawal is easily managed, for example, by tapering off a patient's dosage. For instance, Endo's CME, *Persistent Pain in the Older Adult*, taught that withdrawal can be avoided by tapering off dosage by 10-20% daily for ten days.

159. The 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat Chronic Pain Now!" advised potential opioid users that tolerance to opioids is "easily remedied" and that "[a]ll patients can be safely taken off opioid medication if the dose is slowly tapered down by their doctor."[50]

160. Janssen's training materials asserted that Nucynta ER has a low incidence of withdrawal symptoms, based on a study of withdrawal symptoms two to four days after discontinuing use (when, in fact, the symptoms peak earlier than that).

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[49] *See, e.g.*, Cindy L. Kidner, Ph.D., et al., *Higher Opioid Doses Predict Poorer Functional Outcome in Patients with Chronic Disabling Occupational Musculoskeletal Disorders*, 91 J. BONE JOINT SURG. AM. 919 (2009).

[50] BRADLEY S. GALER, M.D. & CHARLES E. ARGOFF, M.D., DEFEAT CHRONIC PAIN NOW! (2010).

161. On its current website, PrescribeResponsibly.com, in an article titled *What a Prescriber Should Know Before Writing the First Prescription*, Janssen states that opioid addiction "can usually be managed" with such tools as Opioid Agreements between the prescribing physician and patient.[51]

162. There is no reliable data, nor has there ever been, supporting the statements made by each Marketing Defendant that gradual tapering would alleviate the risk of withdrawal.

f. Falsehood: Pseudoaddiction

163. Pharmaceutical Marketing Defendants tried to dismiss signs of addiction in patients by using the term "pseudoaddiction," invented by Dr. David Haddox, later Vice President of Health Policy at Purdue. Pseudoaddiction was a term used for patients showing signs of addiction; Defendants explained that what these patients were actually exhibiting was "under-treated pain."

164. With no reliable data, the Marketing Defendants grabbed hold of the concept of pseudoaddiction, with the intent and result that treating physicians would ignore signs of actual addiction in their patients (such as seeking early refills, agitation, etc.). Instead of advising the treating physician that the patient is likely in the throes of addiction, the Marketing Defendants advocated that the patient was still undertreated and should be prescribed a higher potency of the opioid.

165. Janssen sponsored, funded, and edited a website publication entitled *Let's Talk Pain*, which stated "pseudoaddiction refers to patient behaviors that may occur when pain is

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[51] *See* Howard A. Heit, M.D. & Douglas L. Gourlay, M.D., *What a Prescriber Should Know Before Writing the First Prescription*, PRESCRIBE RESPONSIBLY, https://www.prescriberesponsibly.com/articles/before-prescribing-opioids (last updated July 2, 2015).

under-treated[.] . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

166. While the term "pseudoaddiction" is no longer prevalent and not currently posted on any of the Marketing Defendants' websites, it was in common use and widely disseminated to physicians through at least 2012. Upon information and belief, as a result of the Marketing Defendants' false information campaign, the signs of addiction in opioid-treated patients are still being misconstrued as pseudoaddiction in the community of practicing physicians, including those physicians in Ohio who serve the population of MetroHealth.

167. There never was any scientifically valid evidence for the concept of pseudoaddiction. The Marketing Defendants knew there was no scientific basis for the concept. The statements about it by the Marketing Defendants were false when made.

3. Means of Disinformation

168. Marketing Defendants strengthened the effects of their misinformation by disseminating it through varied sources in a number of settings, targeting both doctors and patients.

169. Marketing Defendants have poured significant resources into branded advertisements for their own particular opioids. In 2011, Marketing Defendants spent over $14 million advertising in medical journals, including $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.[52]

[52] While Actavis spent less than $100,000 and Cephalon spent nothing on medical advertisement in 2011, these companies' expenditures peaked earlier, with Actavis spending $11.7 million in 2005 and Cephalon spending about $4 million over 2007 and 2008.

170. These advertisements have been run in publications aimed at pain specialists (*e.g.*, JOURNAL OF PAIN, CLINICAL JOURNAL OF PAIN), as well as those aimed at the entire medical community (*e.g.*, JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION).

171. These advertisements have contained misleading claims about Marketing Defendants' opioid products. For example, a 2005 Purdue advertisement in the JOURNAL OF PAIN described OxyContin as an "around-the-clock analgesic . . . for an extended period of time." The advertisement featured a man and boy fishing and proclaimed that "*There Can Be Life With Relief*," falsely suggesting (on both counts) that OxyContin provides effective long-term pain relief and functional improvement. Endo's Opana ER was advertised with photos of people engaged in demanding jobs, suggesting that the drug could provide long-term relief and functional improvement.

172. Since Insys entered the opioid pain market in 2012, after many of these means to disseminate false information were already under way, it is not known at this time to what extent Insys participated in them. Upon information and belief, Insys was able to effectively sell Subsys off-label due to the wide dissemination of misinformation propagated by the other Marketing Defendants.

a. Unsupported Research

173. Marketing Defendants have misrepresented scientific research and evidence surrounding the addictiveness of their pharmaceutical products.

174. Marketing Defendants led people to reasonably believe that they had tested the safety and efficacy of opioids for long-term use by creating a body of false, misleading, and unsupported literature about opioids that appeared to be the result of independent, objective research and was thus more likely to shape the perceptions of prescribers, patients, and payors.

175. Marketing Defendants coordinated the timing and publication of manuscripts, abstracts, posters, oral presentations, educational materials in peer-reviewed journals, and other publications to support the launch and sales of their drugs. Marketing Defendants' internal documents show plans to submit research papers and "studies" to long lists of journals, including back-up options and last resort "fast-track" application journals that they could use if the pending paper was rejected everywhere else.

176. Marketing Defendants worked to ensure that favorable articles were disseminated and cited widely in medical literature, even where references distorted the significance or meaning of the underlying study. One of the most frequently used distortions is the instance of the five-sentence Porter/Jick Letter written to the NEJM in 1980 by Dr. Hershel Jick and his assistant, Ms. Jane Porter.

177. In 1980, Dr. Jick and his assistant, Ms. Porter, who both worked at the Boston University Medical Center, sent the Porter/Jick Letter to the prestigious NEJM:

> ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS
>
> To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.
>
> Jane Porter
> Hershel Jick, M.D.
> Boston Collaborative Drug
> Surveillance Program
> Boston University Medical Center

Waltham, MA 02154.[53]

178. Marketing Defendants and their Front Groups twisted this letter and misused it as scientific confirmation for their assertion that widespread and long-term opioid use does not pose a substantial threat of addiction. The Marketing Defendants knew, but failed to disclose, the material information that undermined the validity of the Porter/Jick Letter for the sweeping proposition for which it was cited.

179. Marketing Defendants knowingly misrepresented the findings and scientific value of the Porter/Jick Letter in several ways:

(a) By omitting the fact that Ms. Porter and Dr. Jick's observations were made in a letter to the editor, and implying – or outright stating – that the results were the published results of a peer-reviewed scientific clinical trial study, they misrepresented the scientific validity of its findings;

(b) The Porter/Jick Letter, written, in 1980, referred to the use of opioids for acute pain in hospitalized patients. Nevertheless, Marketing Defendants cited the Porter/Jick Letter as evidence for the proposition that opioids pose a low risk of addiction in all contexts, including long-term use for chronic pain;

(c) Since the Porter/Jick Letter was based on chart reviews of hospitalized patients, there is no level of confidence that patients were assessed for signs of addiction. Thus, there may have been false negatives;

(d) The Porter/Jick Letter is written about patients who were given a few opioid doses ***in a hospital***, rather than those who were given prescriptions to take home.

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[53] Jane Porter & Hershel Jick, M.D., *Addiction Rare in Patients Treated with Narcotics*, 302 NEW ENG. J. MED. 123 (1980), www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

Nonetheless, it was trumpeted by Marketing Defendants as scientific evidence that opioids pose a low risk of addiction when used long-term; and

(e) There is no evidence that these patients were followed up with after leaving the hospital regarding the presence of any addiction. but it was cited by Marketing Defendants as showing that opioids pose no long-term risk of addiction.

180. Marketing Defendants mis-cited the Porter/Jick Letter again and again as evidence of the minimal risk of addiction from using opioids as a treatment for chronic pain, despite its limited credibility and existence of much more significant evidence to the contrary.

181. Two papers funded by Purdue in 1998 showed that between 8-13% of patients studied subsequently became addicted to opioids. Ignoring this study, the Porter/Jick Letter was cited and relied upon in two CME courses put on by Purdue and Endo in 2012 to support the assertion that opioids are not addictive.

182. The Porter/Jick Letter was not extensively cited as evidence of opioids' low risk of addiction until it first appeared in a 1986 paper by the APS, one of Defendants' Front Groups. From there its use as a tool of misinformation mushroomed. It has been cited over 900 times, in contrast to the other 11 letters to the editor contemporaneously published in the NEJM that were cited a median of 11 times.

183. Dr. Hershel Jick, the primary author, later stated that his own letter had been misused and distorted. He has said that he is "mortified that that letter to the editor was used as an excuse to do what these drug companies did," referring to the fact that "they used this letter to spread the word that these drugs were not very addictive."[54]

[54] Derek Hawkins, *How a Short Letter in a Prestigious Journal Contributed to the Opioid Crisis*, WASHINGTON POST, June 2, 2017, https://www.washingtonpost.com/news/morning-

184. A 2017 statement in the NEJM (probably the first of its kind) was published as a meta-study on the misuse of the Porter/Jick Letter. It states that the letter "was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy," which statement "contributed to the North American opioid crisis[.]"[55]

185. The 2017 study reports that 80.8% of articles citing the Porter/Jick Letter did not mention that it was limited to the hospital setting; and 72.2% of articles citing it used it to support the conclusion that addiction is rare in patients treated with opioids.

186. Marketing Defendants also worked to discredit or bury negative information. Marketing Defendants – often with the help of third-party consultants – targeted a broad range of media to disseminate their message, including negative review articles, letters to the editor, commentaries, case-study reports, and newsletters disparaging reports of the link between opioids and addiction.

187. Marketing Defendants' strategies were intended to, and did, knowingly and intentionally distort the truth regarding the risks, benefits, and superiority of opioids for chronic pain relief, resulting in distorted prescribing patterns.

b. Key Opinion Leaders

188. Marketing Defendants used KOLs (who are generally distinguished physicians and neutral sources of guidance in their medical field), as sources of pro-opioid misinformation for regular practicing doctors, including those in the State of Ohio.

189. The KOLs have been central to the Marketing Defendants' diffuse marketing efforts. KOLs have written, consulted on, edited, and lent their names to books and articles and

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mix/wp/2017/06/02/how-the-opioid-crisis-traces-back-to-a-five-sentence-scholarly-letter-from-1980/?utm_term=.836d02c52301.

[55] Pamela T.M. Leung, B.Sc. Pharm., et al., *A 1980 Letter on the Risk of Opioid Addiction*, 376 NEW ENG. J. MED 2194 (2017).

given speeches and CMEs supportive of chronic opioid therapy. They have served on committees that developed treatment guidelines strongly encouraging the use of opioids to treat chronic pain and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Marketing Defendants were able to exert control over each of these modalities through their KOLs.

190. In exchange for these services of the KOLs, Marketing Defendants provided them with money, prestige, recognition, research funding, and avenues to publish. This positioned the KOLs to exert even more influence in the medical community.

191. Opioid makers were not the first to mask their deceptive marketing efforts in purported science. The tobacco industry also used KOLs in its efforts to persuade the public and regulators that tobacco was not addictive or dangerous. For example, tobacco companies funded a research program at Harvard and chose as its chief researcher a doctor who had expressed views in-line with the industry's views. He was dropped when he criticized low-tar cigarettes as potentially more dangerous and later described himself as a pawn in the industry's campaign.

192. Marketing Defendants cultivated and promoted only those KOLs who could be relied upon to help broaden the chronic pain opioid therapy market. Marketing Defendants selected, funded, and elevated those doctors whose public positions were unequivocally supportive of using opioids to treat chronic pain. These doctors' professional reputations were then dependent on continuing to promote a pro-opioid message, even in activities not directly funded by the drug companies.

193. Marketing Defendants cited and promoted favorable studies or articles by these KOLs. By contrast, Marketing Defendants did not disseminate the publications of doctors critical of the use of chronic opioid therapy. One prominent KOL sponsored by many of the

Marketing Defendants, Dr. Russell Portenoy, stated that he was told by a drug company that research critical of opioids (and the doctors who published that research) would never obtain funding.

194. Some KOLs have even gone on to become direct employees and executives of Marketing Defendants, like Dr. Haddox, Purdue's Vice President of Health Policy, or Dr. Bradley Galer, Endo's former Chief Medical Officer.

195. Marketing Defendants provided substantial opportunities for KOLs to author articles or research studies on topics Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature. As described by Dr. Portenoy, drug companies would approach him with a study that was well under way and ask if he would serve as the study's author. Dr. Portenoy regularly agreed.

196. Marketing Defendants also paid KOLs to serve as consultants or on their advisory boards and give talks or present CMEs, often over meals or at conferences. Since 2000, Cephalon, for instance, has paid doctors more than $4.5 million for programs relating to its opioids.

197. Marketing Defendants kept close tabs on the content of the misleading materials published by these KOLs. In many instances, they also scripted what these KOLs said – as they did with all their recruited speakers.

198. There was a group of KOLs who received funding and benefits from all the Marketing Defendants, who participated in an enterprise to pay these KOLs to disseminate misinformation about the safety and efficacy of opioids as a treatment for chronic pain, in order to enable the Marketing Defendants to unlawfully expand their profits.

199. Dr. Portenoy received research support, counseling fees, and honoraria from Marketing Defendants Purdue, Cephalon, Janssen, and others. He was also president of APS and a board member of APF.

200. Dr. Lynn Webster was the author of numerous CMEs sponsored by Purdue, Cephalon, and Endo. He was also president of the Front Group American Academy of Pain Medicine ("AAPM") and a board member of APF. Dr. Webster has disclosed receiving "honoraria, consultant fees and/or travel expenses" from Insys, Mallinckrodt, and Cephalon.[56]

201. Dr. Scott Fishman was a KOL who authored *Responsible Opioid Prescribing*, a publication sponsored by Marketing Defendants Purdue and Cephalon. Dr. Fishman was also president of APF and president of AAPM.

202. Dr. Perry Fine was a KOL who received funding from Marketing Defendants Purdue, Cephalon, Janssen, and Endo. He was also president of AAPM and a board member of APF.

c. Continuing Medical Education

203. Ohio physicians are required to attend no less than 100 hours of CMEs and attest to their attendance every two years in order to keep their medical licenses. R.C. 4731.282. Marketing Defendants sponsored CMEs and made sure that the content supported their position on opioids. They were thereby able to promulgate their teaching to a large number of doctors that they should be prescribing more opioids.

204. Because CMEs are typically delivered by KOLs, who are highly respected in their fields and thought to reflect these physicians' medical expertise and "cutting edge" practices, these CMEs can be especially influential to doctors.

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[56] Lynn R. Webster MD, *Opioid-Induced Constipation*, 16 PAIN MEDICINE S16 (2015), *available at* https://onlinelibrary.wiley.com/doi/full/10.1111/pme.12911.

205. The countless doctors and other healthcare professionals who participated in these accredited CMEs constituted an enormously important audience for opioid reeducation. Marketing Defendants targeted general practitioners who were especially susceptible to Marketing Defendants' deceptions because of their lack of specialized training in pain management and the likelihood that they would treat patients seeking medical treatment for pain management issues.

206. These CMEs, often with names related to treatment of chronic pain, inflated the benefits of opioids, omitted or downplayed their risks, and focused on opioids to the exclusion of alternative treatments.

207. The influence of Marketing Defendants' funding on the content of these CMEs is clear. One study by a Georgetown University Medical Center professor compared the messages retained by medical students who reviewed an industry-funded CME article on opioids versus another group who reviewed a non-industry-funded CME article. The industry-funded CME did not mention opioid-related death once; the non-industry-funded CME mentioned opioid-related death 26 times.

208. Students who read the industry-funded article noted more frequently the impression that opioids were underused in treating chronic pain. The "take-aways" of those reading the non-industry-funded CME included the risks of death and addiction much more frequently than those of the other group.

209. Neither group could accurately identify whether the article they read was industry-funded, making clear the difficulty medical practitioners (the audience for CMEs) have in screening and accounting for source bias.[57]

210. By sponsoring CME programs presented by Front Groups like AAPM, APF, and others, like PAINWeek, Marketing Defendants could expect messages to be favorable to them, as these organizations were financially dependent on Marketing Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Marketing Defendant-driven content in these CMEs had a direct and immediate effect on prescribers' views on opioids.

d. Treatment Guidelines

211. Marketing Defendants produced treatment guidelines for doctors. Such guidelines were crucial for giving legitimacy to extensive opioid prescriptions and providing a framework within which doctors would feel comfortable prescribing them. These guidelines are also cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications.

(i) Federation of State Medical Boards

212. The Federation of State Medical Boards ("FSMB") is an organization representing the various state medical boards in the United States, including the State Medical Board of Ohio, which have the power to license doctors, investigate complaints, and discipline physicians. The FSMB finances opioid- and pain-specific programs through grants from Marketing Defendants.

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[57] Adriane Fugh-Berman MD, *Marketing Messages in Industry-Funded CME*, PHARMED OUT (June 25, 2010), http://www.pharmedout.org/pdf/Conf2010/Fugh-BermanPrescriptionforConflict6-25-10.pdf.

213. In 1998, the FSMB developed its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), which FSMB conceded was produced "in collaboration with pharmaceutical companies." From 1997 to 2013, FSMB received more than $2 million from the Marketing Defendants (other than Insys). The FSMB Guidelines taught that opioids were "essential" for treatment of chronic pain, including as a first prescription option. The FSMB Guidelines failed to mention risks relating to respiratory depression and overdose and discussed addiction only in the sense that "inadequate understanding" of addiction can lead to "inadequate pain control."

214. These so-called guidelines created an environment wherein patients being treated with pain medications developed the expectation that they should feel no pain whatsoever during treatment. Physicians, nurses, and clinicians employed by MetroHealth continually have to work against this expectation that there should be zero pain as opposed to tolerable pain. Such patient education efforts put MetroHealth in a tenuous position, since it stands to lose funding if patients give bad patient-satisfaction ratings over MetroHealth's treatment and control of pain.

215. The publication of *Responsible Opioid Prescribing*, a book adapted from the FSMB Guidelines, was backed largely by Marketing Defendants, including Cephalon, Endo, and Purdue. The FSMB financed the distribution of *Responsible Opioid Prescribing* by its member boards by contracting with drug companies, including Endo and Cephalon, for bulk sales and distribution to sales representatives (for distribution to prescribing doctors). A total of 163,131 copies of *Responsible Opioid Prescribing* were distributed to state medical boards, including the Ohio State Board of Medicine (and through the boards, to practicing doctors), and the FSMB earned approximately $250,000 in revenue and commissions from their sale.

216. The FSMB Guidelines conveyed the message that "inadequate pain control" would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented.

217. Through the FSMB Guidelines, the Marketing Defendants were able to turn doctors' fear of discipline on its head – doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught that they would be punished instead if they failed to prescribe opioids to their patients with pain.

(ii) AAPM/APS Guidelines

218. AAPM and APS are professional medical societies, each of which received substantial funding from Marketing Defendants from 2009 to 2013 (with AAPM receiving well over $2 million).

219. AAPM issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids for treating chronic pain and claimed that the risk of addiction to opioids was low.[58] The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue and subsequently became Vice President of Health Policy at Purdue. Dr. Portenoy, one of the main KOLs who received funding from Marketing Defendants Janssen, Cephalon, Endo, and Purdue, was the sole consultant. The consensus statement formed the foundation of the FSMB Guidelines. That statement was actively distributed by AAPM until 2012.

[58] The American Academy of Pain and the American Pain Society, *The Use of Opioids for the Treatment of Chronic Pain*, 13 CLINICAL J. PAIN 6 (1997), *available at* http://www.jpain.org/article/S1082-3174(97)80022-0/pdf.

220. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines"), that continued to recommend the use of opioids to treat chronic pain.[59] Fourteen of the 21 panel members, who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

221. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past substance use disorder histories.

222. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the AAPM/APS Guidelines were influenced by contributions that drug companies, including Marketing Defendants, made to the sponsoring organizations and committee members.

223. The AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids. The AAPM/APS Guidelines have been cited 732 times in academic literature, are still available online, and were reprinted in the JOURNAL OF PAIN.

224. Defendants widely referenced and promoted the AAPM/APS Guidelines without disclosing the acknowledged lack of evidence to support them.

(iii) American Geriatrics Society

225. The American Geriatrics Society ("AGS"), a nonprofit organization serving healthcare professionals who work with the elderly, disseminated guidelines regarding the use of opioids for chronic pain in 2002, *The Management of Persistent Pain in Older Persons*

[59] Roger Chou, et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10 J. PAIN 113 (2009).

(hereinafter, "2002 AGS Guidelines"), and 2009, *Pharmacological Management of Persistent Pain in Older Persons* (hereinafter, "2009 AGS Guidelines").

226. The 2009 AGS Guidelines recommended that "[a]ll patients with moderate to severe pain . . . should be considered for opioid therapy" and stated that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[60] These recommendations are not supported by any study or any other reliable scientific evidence. Nevertheless, they have been cited 278 times in Google Scholar since their 2009 publication.

227. AGS contracted with Marketing Defendants Endo, Purdue, and Janssen to disseminate the 2009 AGS Guidelines and sponsor CMEs based on them. The Marketing Defendants were aware of the content of the 2009 AGS Guidelines when they agreed to provide funding for these projects.

228. The 2009 AGS Guidelines were first published online on July 2, 2009. AGS submitted grant requests to Marketing Defendants, including Endo and Purdue, beginning July 15, 2009. Internal AGS discussions in August 2009 reveal that AGS did not want to receive up-front funding from Marketing Defendants, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the 2009 AGS Guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they had approved the message, AGS effectively ceded significant control to these companies. Endo, Janssen, and Purdue all agreed to provide support to distribute the 2009 AGS Guidelines.

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[60] B. Ferrell, et al., *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. AM. GERIATR. SOC'Y 1331, 1339, 1342 (2009), *available at* https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1532-5415.2009.02376.x.

229. Five of ten of the experts on the 2009 AGS Guidelines panel disclosed financial ties to Marketing Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Marketing Defendants, receiving grants from Marketing Defendants, and investing in Marketing Defendants' stock.

230. As noted *infra* ¶¶249-250, the recommendations (in this case, treatment guidelines) of those organizations not financed by Marketing Defendants stood in marked contrast to those financed by the Defendants.

e. Front Groups and Unbranded Advertising

231. Marketing Defendants Purdue, Endo, Janssen, and Cephalon collectively used unbranded, third-party marketing (through KOLs and Front Groups) as part of their national marketing strategies for their branded drugs. Unbranded advertising had the dual advantage of having an appearance of independence and credibility and not being subject to the regulations promulgated by the FDA for branded advertising. The purpose of the FDA regulations on branded advertising, 21 U.S.C. §352(a) and 21 C.F.R. §§1.21(a), 202.1(e)(3), 202.1(e)(6), is to encourage truthful advertising.

232. Defendants published print advertisements in a broad array of medical journals, ranging from those geared to a wider audience, such as the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, to those targeted more at specialists, such as the JOURNAL OF PAIN. In 2011 alone, Defendants' advertising budgets exceeded $14 million on the medical journal advertising of opioids, which was nearly three times what they spent in 2001.

233. Marketing Defendants Purdue, Cephalon, Janssen, Endo, and Actavis engaged in a series of actions designed to thwart federal advertising guidelines, market themselves by way of seemingly neutral third parties, and appear distanced from these organizations while simultaneously funneling large amounts of money into them. By doing so, they were able to

engage in a multi-pronged effort to misrepresent the risks and overstate the benefits of using opioids. These Marketing Defendants were also able to change prescribing practices through materials that appeared not to be marketing materials.

234. One part of this approach was to influence the stances of Front Groups by heavily contributing to the organizations' income. Marketing Defendants then turned around and cited materials produced by these groups as evidence of their positions.

(i) APF's Role as a Front Group for Defendants' Deceptive Marketing

235. APF was a prominent Front Group for Marketing Defendants. The group's name is meant to sound official and impartial, but in fact, this organization was a front for promotional material and advocacy on behalf of the Marketing Defendants.

236. Between 2007 and until its closure in May 2012, APF received upwards of $10 million from Marketing Defendants. In 2009 and 2010, it received from them more than 80% of its operating budget. In 2010, for example, APF received more than $1 million from Endo.

237. APF issued "education guides" for patients, policymakers, and the news media that advocated the benefits opioids provided for chronic pain and trivialized their risks, particularly the risk of addiction. APF engaged in a significant multimedia campaign through television, radio, and the internet to purportedly "educate" patients about their "right" to pain treatment with opioids.

238. The publications available from APF extolled the benefits of opioids, and these publications were underwritten by Marketing Defendants Purdue, Cephalon, Janssen, and Endo. For example, one board member published a study in 2010 sponsored by Cephalon, finding that Cephalon's drug Fentora was "generally safe and well-tolerated" in non-cancer patients, even though it was only approved for severe cancer pain.

239. APF held itself out as an independent patient advocacy organization. In reality, APF functioned largely as an advocate for the interests of Defendants, not patients. APF engaged in grassroots lobbying efforts against various legislative initiatives that might limit opioid prescribing, exemplifying APF's true interest, which was to make money for the manufacturers, and ignoring patient pain concerns.

240. In practice, APF operated in close collaboration with Marketing Defendants. APF submitted grant proposals seeking to fund activities and publications they suggested and assisted in marketing projects for them.

241. APF and APS submitted *amicus* briefs in defense of opioids: in one case, in support of Defendant Purdue; in another, in support of a doctor on trial for over-prescribing pain medication (who was subsequently found guilty of 16 counts of drug trafficking).

242. By 2011, APF was entirely dependent on incoming grants from Marketing Defendants Purdue, Cephalon, Endo, and others for funding, which also thereby enabled APF to avoid using its line of credit. APF board member and KOL Dr. Portenoy, explained that the lack of funding diversity was one of the biggest problems at APF.

243. All of APF's programs and materials were intended to, and did, reach a national audience, including the patient population of MetroHealth.

244. A 2012 U.S. Senate Finance Committee investigation between manufacturers and APF resulted in an abrupt halt to this funding. APF's board dissolved the group within days of this investigation.

(ii) The Role of Other Front Groups in Defendants' Deceptive Marketing

245. AAPM similarly has received more than $2 million from opioid manufacturers since 2009. This group issues treatment guidelines and hosts CME courses, while espousing

positions consistent with opioid manufacturers. Presidents of this organization include many of the KOLs mentioned above. A yearly meeting put on by AAPM allows the group to interface with opioid manufacturers, who pay to present "medical education programs" to AAPM and attending doctors.

246. Other Front Groups include the University of Wisconsin Pain & Policy Studies Group, which received $2.5 million from opioid manufacturers to lobby and otherwise promote opioid use; and APS, incorporated in 1977, whose primary corporate supporter is pharmaceutical manufacturer Mallinckrodt. Similarly, the Pain Care Forum, a Front Group led by the lead lobbyist for Purdue, comprises a group of over 100 drug manufacturers (including each Marketing Defendant) and advocacy groups that met on a monthly basis to coordinate efforts to influence legislation concerning prescription pain medications on both federal and state levels.

247. These Front Groups provided important services for the Marketing Defendants. They prepared and disseminated unbranded materials promoting the use of opioids to doctors and the public, including by conducting CMEs and issuing treatment guidelines for doctors, and by outreach targeting particularly vulnerable groups, such as veterans and elderly people. They also advocated against regulatory guidelines that would limit opioid prescriptions and responded negatively to journal articles not supporting the use of opioids. The significant funding and regular interfacing between these sets of organizations ensured that the Front Groups would issue messages supporting the positions of the opioid manufacturers.

248. Defendants Purdue, Endo, Janssen, Cephalon, Mallinckrodt, and Actavis collectively exercised substantial control over the content of the messages third parties generated and disseminated and distributed certain of those materials themselves. These Defendants took an active role in guiding, reviewing, and approving many of the misleading statements issued by

these third parties, ensuring that Marketing Defendants were consistently aware of their content. By funding, directing, editing, and distributing these materials, Marketing Defendants exercised control over their deceptive messages and acted in concert with these third parties to fraudulently promote the use of opioids for the treatment of chronic pain.

249. The behavior and positions of those groups that did not accept funding from manufacturers contrast significantly with that of the Front Groups. The American Society of Interventional Pain Physicians only recommends high doses of long-acting opioids "in specific circumstances with severe intractable pain," along with "continuous adherence monitoring, in well-selected populations, in conjunction with or after failure of other modalities of treatments with improvement in physical and functional status and minimal adverse effects."[61]

250. The American College of Occupational and Environmental Medicine similarly discourages "routine use of opioids in the management of patients with chronic pain," though conceding that for some patients it may be appropriate.[62] The U.S. Department of Veteran Affairs ("VA") and the U.S. Department of Defense ("DoD") note risks of abuse and misuse, and "the lack of solid evidence based research on the efficacy of long-term opioid therapy."[63]

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[61] Bradley W. Wargo, DO, et al., *Am. Soc'y of Interventional Pain Physicians (ASIPP), guidelines for responsible opioid prescribing in chronic non-cancer pain* (pts. 1 & 2), 15 PAIN PHYSICIAn S1 (2012), *available at* https://www.ncbi.nlm.nih.gov/pubmed/22786448 & https://www.ncbi.nlm.nih.gov/pubmed/22786449.

[62] AM. C. OF OCCUPATIONAL & ENVTL. MED., ACOEM'S GUIDELINES FOR THE CHRONIC USE OF OPIOIDS (2011), available at https://www.nhms.org/sites/default/files/Pdfs/ACOEM%202011-Chronic%20Pain%20Opioid%20.pdf.

[63] THE MANAGEMENT OF OPIOID THERAPY FOR CHRONIC PAIN WORKING GROUP, VA/DOD CLINICAL PRACTICE GUIDELINE FOR MANAGEMENT OF OPIOID THERAPY FOR CHRONIC PAIN (version 2.0, 2010), *available at* https://www.va.gov/painmanagement/docs/cpg_opioidtherapy_summary.pdf.

f. Defendants Inappropriately Used Their Sales Force and "Speakers Bureaus" to Unfairly and Deceptively Promote Use of Their Drugs

251. Like most drug manufacturers, the Marketing Defendants made extensive use of their sales force – sometimes called "detailers" – to meet with physician groups one-on-one and promote their products through intimate settings with promotions being advanced by paid speakers. The degree to which the Defendants organized their sales force to "lock-step" sell their products, based on falsehoods and material omissions, is what rendered their marketing efforts unlawful.

252. Defendants' marketing plans, which often operated in parallel to one another, targeted physician groups far afield from pain specialists and anesthesiologists (or cancer doctors) to include physician groups, such as general practice physicians, sports medicine physician groups, etc., with no correlation to the demonstrated needs of the physicians' patients for opioid therapy or to the risk of addiction.

253. The expanded market of prescribers tended to be, as a group, less informed about opioids and more susceptible to Defendants' marketing. The prescribers included nurse practitioners and physician assistants who were "share acquisition" opportunities because they were "3x more responsive than MDs to detail," according to an Endo business plan.

254. The expanded market also included internists and general practitioners with a stated goal, for example, according to an Actavis plan, to move beyond "Kadian loyalists" to an "expanded audience" of "low morphine writers."

255. Each Marketing Defendant relied upon "influence mapping," which meant using decile ranking to identify high-volume prescribers, so that the manufacturer's sales force would get the biggest impact from sales calls. Defendants also closely monitored a doctor's prescribing after a sales representative's visit to allow them to fine-tune their messaging.

256. Each Defendant studiously trained its sales representatives – through detailed action plans, trainings, tests, scripts, role-plays, and supervision tag-alongs – to ensure that the individual sales representatives stayed strictly on script, which involved selling their opioids for off-label uses.

257. In addition to the sales calls, sales representatives were required to identify "product loyalists" – who were high prescribers of drugs – to be selected to be speakers on behalf of the Marketing Defendants and be invited to give speeches to their peers proclaiming the effectiveness of the respective manufacturer's opioid.

258. The Marketing Defendants all tracked the effectiveness of the speaker's program by monitoring the prescription writing of the attending physicians after said program. It was an effective strategy. Endo noted that "physicians who came into our speaker programs wrote more prescriptions for Opana ER after attending than before."

259. Defendants devoted substantial resources to these direct sales contacts with prescribers. In 2014, Defendants collectively spent $168 million on detailing branded opioids to physicians nationwide. This figure includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. The total figure is more than double Defendants' collective spending on detailing in 2000. The detailers' role in Defendants' overall promotional efforts was also carefully calibrated; Endo, for example, found that devoting 61% of its marketing budget to sales representatives reflected an "[a]ppropriate combination of personal . . . and non-personal . . . selling initiatives."

260. Defendants spent hundreds of millions of dollars promoting their opioids through their large sales forces because their monitoring showed that the sales forces' face-to-face meetings with prescribers had a significant influence on prescribing rates. As a routine matter,

the Defendants incentivized their sales representatives to sell by basing their compensation on a low salary/high commission format.

261. Upon information and belief, hundreds or thousands of visits from sales representatives from each of the Marketing Defendants were made to prescribers in Cuyahoga County, where the message regarding the use and safety of opioid therapy for the prescribers' patients was untethered from any scientific basis, as the Defendants well knew.

g. Direct-to-Consumer Marketing

262. Marketing Defendants targeted patients, so that they would ask doctors for those medications specifically. Endo's research, for example, found that such direct-to-consumer communications resulted in greater patient "brand loyalty," with longer durations of Opana ER therapy and fewer discontinuations. Patient-focused advertising, especially direct-to-consumer marketing, is seen by marketing experts within the pharmaceutical industry as substantially valuable in "increas[ing] market share . . . by bringing awareness to a particular disease that the drug treats."[64] An Actavis marketing plan, for example, noted that "[d]irect-to-consumer marketing affects prescribing decisions."

263. Defendants marketed to consumers through patient-focused "education and support" materials. These took the form of pamphlets, videos, or other publications that patients could view in their physicians' offices. Endo also targeted employer and workers' compensation plan initiatives. This marketing was intended to, and did, result in patients requesting the opioids in reliance on Defendants' statements that contained falsehoods and material omissions.

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[64] Kanika Johar, *An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices*, 76 ALBANY L. REV. 299, 308 (2013), *available at* http://www.albanylawreview.org/Articles/Vol76_1/76.1.0299%20Johar.pdf.

264. Defendants also recognized the obstacle that out-of-pocket costs to patients posed to their bottom line sales figures. They overcame this obstacle by providing patients financial assistance with their insurance co-payments through vouchers and coupons distributed by Defendants' sales representatives when they visited with prescribers. For example, in 2012, Janssen planned to distribute 1.5 million savings cards worth $25 each.

265. Defendant Insys brought the effort to get insurance to pay for its product to an entirely new level of fraud. As the *Fueling an Epidemic* Senate report describes, Insys created a separate department, the Insys Reimbursement Center ("IRC"), designed to obtain quick approvals for insurance reimbursement for Insys's product, Subsys, which is an orally administered spray of fentanyl. The IRC unit exercised fraud and deception (such as pretending to be calling from a physician's office and falsely representing that the prescription was for a cancer patient, which was the only FDA-approved indication for Subsys). The head of the IRC unit, Elizabeth Guerrieri, pled guilty to "having conspired to defraud insurers" (wire fraud) in June 2017 in the District Court for the District of Massachusetts.

(i) The Elderly

266. Defendants have promoted the unfounded notion that the elderly are particularly unlikely to become addicted to opioids. The 2009 AGS Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as "exceedingly low in older patients with no current or past history of substance abuse." There is not now, nor has there ever been, any scientifically based evidence to support this statement.

267. On the contrary, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.[65]

[65] Kate M. Dunn, et al., *Opioid Prescriptions for Chronic Pain and Overdose: A Cohort Study*, 152 ANNALS INTERNAL MED. 85 (2010).

268. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, greater risk for hospitalizations, increased vulnerability to adverse drug effects and interactions, such as respiratory depression, and a significantly higher rate of deaths, heart attacks, and strokes than users of NSAIDs.

269. Defendants' targeted marketing to the elderly, and the absence of cautionary language in their promotional materials, flies in the face of scientific evidence and their own labels and creates a heightened risk of serious injury to elderly patients.

270. Defendants' efforts have paid off. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults between the ages of 40 and 59.

(ii) Veterans

271. Veterans, too, were specifically targeted for Defendants' misleading marketing. A 2008 survey showed that prescription drug abuse among military personnel had doubled from 2002 to 2005, and then nearly tripled again over the next three years.[66]

272. In 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills – four times as many as they had written in 2001. Further, one-third of veterans who were prescribed opioids, as of 2012, remained on take-home opioids for more than 90 days. Although many of these veterans are returning from service with traumatic injuries, the increase in opioid prescribing is disproportionate to the population and, in far too many cases, unsuited for their treatment.

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[66] RTI INTERNATIONAL, 2008 DEPARTMENT OF DEFENSE SURVEY OF HEALTH RELATED BEHAVIORS AMONG ACTIVE DUTY MILITARY PERSONNEL (2009), *available at* https://prhome.defense.gov/Portals/52/Documents/RFM/Readiness/DDRP/docs/2009.09%202008%20DoD%20Survey%20of%20Health%20Related%20Behaviors%20Among%20Active%20Duty%20Military%20Personnel.pdf.

273. Among former service members receiving VA services nationally in a single year (2005), 1,013 died of an accidental drug overdose – almost double the rate of the civilian population (19.85 people out of 100,000 per year vs. 10.49 people out of 100,000 per year).[67]

274. Opioids are particularly dangerous to veterans. According to a study published in the 2013 JOURNAL OF AMERICAN MEDICINE, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries; and 40% of veterans with post-traumatic stress disorder received opioids and benzodiazepines (anti-anxiety drugs) that, when mixed with alcohol, can cause respiratory depression and death.

275. According to a VA Office of Inspector General report, despite the risks, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines.[68]

276. As with elderly patients, Defendants both purposefully sought to increase opioid prescribing to this vulnerable group and omitted from their promotional materials the known, serious risks opioids pose to them.

277. *Exit Wounds*, a 2009 publication sponsored by Purdue, distributed by APF with grants from Janssen and Endo, and written as if it were a personal narrative of one veteran, describes opioids as "underused" and the "gold standard of pain medications" and fails to disclose the risk of addiction, overdose, or injury.

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[67] Amy S.B. Bohnert, Ph.D., et al., *Accidental Poisoning Mortality Among Patients in the Department of Veterans Affairs Health System*, 49 MED. CARE 393 (2011), *available at* https://journals.lww.com/lww-medicalcare/Abstract/2011/04000/Accidental_Poisoning_Mortality_Among_Patients_in.11.aspx.

[68] U.S. DEP'T OF VETERANS AFF., OFF. OF INSPECTOR GEN., REP. NO. 14-00895-163, HEALTHCARE INSPECTION – VA PATTERNS OF DISPENSING TAKE-HOME OPIOIDS AND MONITORING PATIENTS ON OPIOID THERAPY (2014).

278. *Exit Wounds* states that opioid medications "increase a person's level of functioning" and that "[l]ong experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications."

279. The publication also asserts that "[d]enying a person opioid pain medication because he or she has a history of substance abuse or addiction is contrary to the model guidelines for prescribing opioids, published by the U.S. Federation of State Medical Boards." As laid out above, the FSMB itself received support from Defendants during the time it created and published its guidelines.

280. *Exit Wounds* minimizes the risks of chronic opioid therapy and does not disclose the risk that opioids may have fatal interactions with benzodiazepines, which were taken by a significant number of veterans.[69] The deceptive nature of *Exit Wounds* is obvious when compared to the guidance on opioids published by the VA and DoD in 2010 and 2011. The VA's *Taking Opioids Responsibly* describes opioids as "dangerous." It cautions against taking extra doses and mentions the risk of overdose and the dangers of interactions with alcohol. The list of side effects from opioids includes decreased hormones, sleep apnea, hyperalgesia, addiction, immune system changes, birth defects, and death – none of which is mentioned in *Exit Wounds*.

281. Approximately 74,103 U.S. veterans resided in the geographic area served by MetroHealth, according to the United States Census Bureau, 2012-2016 American Community

[69] FDA draft guidance states that materials designed to target a particular audience should disclose risks particular to that audience. *See* U.S. FOOD & DRUG ASS'N, BRIEF SUMMARY AND ADEQUATE DIRECTIONS FOR USE: DISCLOSING RISK INFORMATION IN CONSUMER-DIRECTED PRINT ADVERTISEMENTS AND PROMOTIONAL LABELING FOR PRESCRIPTION DRUGS (2015), https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm069984.pdf.

Survey 5-Year Estimates,[70] and, upon information and belief, many of these veterans were wrongfully prescribed opioids and received misinformation about their usefulness and safety by reading *Exit Wounds* and other means of public dissemination of misinformation promulgated by Defendants.

4. Purdue-Specific Misrepresentation: The 12-Hour Dosing Lie

282. In the late 1980s, Purdue (a relatively small pharmaceutical company at the time) was facing a serious revenue threat. Its main drug was a morphine pill for cancer patients with the trade name MS Contin. The patent on MS Contin was about to expire, which meant the drug would face serious downward pricing pressure from generics that were likely to enter the market of an opioid treatment for cancer patients.

283. To solve its "vulnerability of the . . . generic threat," Defendant Purdue decided to devote a huge effort and funding into the launch of another opioid product, which it tradenamed OxyContin. OxyContin was classified as an oxycodone similar to Percocet (which was already on the market), but Purdue combined the oxycodone with a time release technique and claimed that the new drug would control pain for up to 12 hours.

284. Purdue's claim that its opioid could provide 12 hours of pain relief was a primary selling point for its new drug. In its 1992 submission to the U.S. Patent Office, Purdue touted that OxyContin was a medical breakthrough that controlled pain for 12 hours "in approximately 90% of patients."

285. Armed with its new product, Purdue launched OxyContin in 1996 after obtaining FDA approval in 1995. A Purdue marketing executive stated in a 1995 internal memo (that was

[70] *American FactFinder*, U.S. Census Bureau, https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.xhtml?src=bkmk (last visited June 25, 2018).

obtained by the LOS ANGELES TIMES and reported in a May 5, 2016 exposé), "[w]e do not want to niche OxyContin just for cancer pain."

286. However, the promise of 12-hour pain relief was not true, which Purdue knew. The effects of OxyContin (both the pain relief and the euphoria) wore off for most of the patients in Purdue's clinical trials well before 12 hours. Many patients would start to crave another dose within eight hours or even less time.

287. OxyContin tablets provide an initial absorption of approximately 40% of the active component. This fact causes two results, both of which made OxyContin particularly addictive. First, the initial rush of almost half of the powerful opioid triggers a powerful psychological response. Thus, OxyContin – which is approximately twice as powerful as morphine – acts more like an immediate-release opioid. Second, since there is less of the drug at the end of the 12-hour dosing periods, many patients begin to experience withdrawal symptoms before the 12 hours expire. The combination of fast onset and end-of-dose withdrawal symptoms makes OxyContin powerfully addictive.

288. Although Purdue was well aware of the shorter duration of the drug's effects for many patients, it withheld this information from prescribing physicians and, to the contrary, instructed its sales force (which by 1997, one year after the drug's launch, had ballooned to over 200) to recommend to prescribers that they increase the strength of the dose rather than its frequency.

289. By use of this falsehood, Purdue kept its competitive advantage of being able to claim that OxyContin gives a full 12 hours of relief, allowing the convenience of twice-a-day dosing.

290. This strategy was a triple win for Purdue. First, the maximum strength 80 milligrams of OxyContin netted Purdue more than $630, rather than the $97 for a 10-milligram bottle. Second, if the patient in the throes of opioid withdrawal started to take the drug at shorter intervals, Purdue could claim it was "not their problem." Third, the increased dose made the drug even more addictive, thereby making it likely that Purdue would have a customer for life.

291. To this day, Purdue continues to misrepresent OxyContin to doctors as a 12-hour drug.[71]

292. The LOS ANGELES TIMES exposé stated that, as of 2014, more than 52% of patients taking OxyContin longer than three months were prescribed doses greater than 60 milligrams a day. Dr. Debra Houry of the CDC stated in 2017 that those doses were "really concerning" because "the higher you go, the more likely you are to die."

5. Insys-Specific Misrepresentation

293. Insys is the next-to-last entrant into the prescription opioid market among the Marketing Defendants, having acquired FDA approval for its drug, tradenamed Subsys, in 2012.

294. As discussed *supra* ¶77, Subsys is a highly addictive synthetic opioid form of fentanyl mouth-spray approved by the FDA for a very limited indication: treatment of

[71] *OxyContin® CII (Oxycodone HCI) Extended- Release Tablets*, PURDUE PHARMA, http://www.purduepharma.com/healthcare-professionals/products/oxycontin (last visited June 25, 2018); *OxyContin®: Highlights of Prescribing Information*, PURDUE PHARMA (Dec. 2016), http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o (OxyContin prescription information); *Medication Guide: OXYCONTIN® (ox-e-KON-tin)(oxycodone hydrochloride) extended-release tablets, CII,* PURDUE PHARMA (Dec. 2016), http://app.purduepharma.com/xmlpublishing/pi.aspx?id=o&medguide=1 (medication guide); *Setting The Record Straight On Oxycontin's FDA-Approved Label*, PURDUE PHARMA (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label (responding to the Los Angeles Times article by doubling down on its claims).

breakthrough cancer pain only in patients who have already been administered other opioids and who have established a tolerance for those opioids.

295. Insys has mounted an aggressive and unlawful off-label marketing strategy for Subsys in violation of the FDCA, 21 U.S.C. §301, *et seq*., knowingly marketing its dangerous product for uses that were not approved by the FDA, which led to the submission of false and improper payment requests to government programs Medicare and Medicaid and indictments and/or pleas of many of its key executives.

296. There is a limited customer base for cancer patients who are already taking morphine to manage cancer pain, but still need an additional boost to treat breakthrough cancer pain. Accordingly, Insys determined to sell its potent and dangerous opioid to a wider class of patients. Their sales force, whose pay was largely dependent on commissions, visited dentists, chiropractors, general practitioners, and others throughout the country, including in Ohio and, upon information and belief, in Cuyahoga County, to market Subsys for a wide variety of ailments, from root canals to back pain.

297. The Senate report, *Fueling an Epidemic*, revealed, among other things, how the Insys sales force was incentivized and indoctrinated to sell Subsys as a safe treatment for many conditions far afield from breakthrough cancer pain. Moreover – and just as dangerously – the sales staff was instructed to induce their physicians to write prescriptions for higher, more expensive doses.

298. Marketing Defendant Insys and Individual Defendant Kapoor knew that the off-label use of Subsys could be fatal, and, at the very least, could lead to addiction in the user. Despite this knowledge, Marketing Defendant Insys unlawfully, recklessly, and with wanton,

willful, and criminal intent continued to market its product for the use of innocent persons for whom it was foreseeable that it would cause grave and perhaps fatal harm.

299. On December 16, 2016, the U.S. Attorney for the District of Massachusetts announced the indictment of six former Insys executives and managers on a host of charges stemming from "a nationwide conspiracy to profit by using bribes and fraud to cause the illegal distribution of a fentanyl spray [*i.e.* Subsys] intended for cancer patients experiencing breakthrough pain." On October 24, 2017, a superseding indictment named and incorporated Individual Defendant Kapoor for his role in that conspiracy.

6. Actavis-Specific Misrepresentation

300. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and mental health," and cause patients to enjoy their lives. The FDA warned Actavis that such claims were misleading, disclaiming: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[72]

301. Actavis disregarded the FDA's 2010 warning and Actavis's sales representatives continued to market the falsehood that prescribing Actavis's opioids would improve patients' ability to function and improve their quality of life.

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[72] Letter from Thomas Abrams, Dir., Director of Div. of Mktg., Adver., & Commc'ns, FDA, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (available at https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf) (Warning letter).

302. Actavis's sales training modules severely downplayed the association between Kadian (and other opioids) and the risk of addiction. A 2010 module represented that "there is no evidence that simply taking opioids for a period of time will cause substance abuse or addiction," and instead, "[i]t appears likely that most substance-abusing patients in pain management practices have an abuse problem before entering the practice." Not only did Actavis falsely suggest the low likelihood of addiction in patients, but it also shifted culpability to the patients, the same people it was entrusted to treat.

7. The Sackler Family Defendants Control And Direct Purdue's Misconduct

303. Purdue's misconduct has been directed and encouraged by its own board of directors. This small group of people controlled Purdue and sanctioned the unlawful conduct perpetrated by those companies.

304. The directors control both Purdue Pharma Inc. and Purdue Pharma L.P. and run the companies as their personal enterprise.

305. Richard Sackler, Jonathan Sackler, Beverly Sackler, Theresa Sackler, Mortimer D.A. Sackler, Kathe Sackler, Ilene Sackler Lefcourt, and David Sackler hold seats on the Board of Directors of Purdue Pharma Inc. Their family owns the company. Richard, Jonathan, Beverly, Theresa, Mortimer, Kathe, and Ilene have been on the board since the 1990s. David has been on the board since 2012.

306. Richard Sackler was as an inventor of the original patent for OxyContin. He testified that the family has made more than $1 billion from OxyContin alone.

307. Each of the Sackler Family Defendants had an obligation, which they violated, to manage Purdue in a lawful manner, rather than allow it to engage in widespread wrongdoing.

308. Upon information and belief, the Sackler Family Defendants are intimately involved in the activities of Purdue Pharma Inc. and Purdue Pharma L.P.

8. Guilty Pleas and Prior Attorney General Settlements with Certain Defendants in Connection with Improper Opioid Marketing

a. Purdue's 2007 Guilty Plea for OxyContin Marketing Misrepresentations

309. In 2007, Purdue and three top executives were indicted in federal court in Virginia and pled guilty to fraud in promoting OxyContin as non-addictive and appropriate for chronic pain.

310. As part of its guilty plea, Purdue admitted that:

> Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows:
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> * * *
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> b. [Purdue] told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;
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> c. [Purdue] sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;
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> d. [Purdue] told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and
>
> e. [Purdue] told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less

abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.[73]

311. Under the plea agreement, Purdue agreed to pay $600 million in criminal and civil penalties – one of the largest settlements in history for a drug company's marketing misconduct.[74] Also, Purdue's CEO, General Counsel, and Chief Medical Officer pled guilty and agreed to pay a total of $34.5 million in penalties.[75]

312. After this plea, Purdue's wrongdoing continued, including its improper marketing campaign, which, along with that of the other Marketing Defendants, conditioned physicians to believe that opioids were a safe and effective means of treating chronic pain long-term.

313. Purdue made many subsequent misleading statements regarding its own opioid products and opioids generally, continuing long after its 2007 guilty plea as alleged herein.

b. Cephalon Enters a Criminal Plea for Off-Label Marketing of Actiq

314. The FDA approved the powerful fentanyl drug Actiq, which was in the form of a lollipop, for use only in opioid-tolerant cancer patients (meaning those patients for whom morphine-based painkillers were no longer effective).

315. From 2001 through at least 2006, Cephalon, the manufacturer of Actiq, promoted the drug for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, in anticipation of changing wound dressings, and/or radiation therapy. Cephalon also promoted Actiq for use in patients who were not opioid-tolerant and for whom the drug could be fatal.

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[73] Statement of John Brownlee, U.S. Att'y, U.S. DOJ, on the Guilty Plea of the Purdue Fredrick Company (May 10, 2007) (available at https://archive.org/stream/279028-purdue-guilty-plea/279028-purdue-guilty-plea_djvu.txt).

[74] *Id*.

[75] *Id*.

316. Using the mantra "pain is pain," Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote the drug for many ordinary types of pain.

317. Cephalon was charged in a criminal violation with off-label selling of Actiq and two of its other drugs by the U.S. Attorney for the Eastern District of Pennsylvania. In a plea agreement with the United Stated entered into in September 2008, Cephalon agreed to pay $50 million in settlement of the off-label marketing charges and, in a separate civil agreement, it agreed to pay $375 million plus interest to resolve Federal False Claims Act ("FCA"), 31 U.S.C. §3729, charges arising from the off-label selling.

318. Acting U.S. Attorney Laurie Magid stated:

> These are potentially harmful drugs that were being peddled as if they were, in the case of Actiq, actual lollipops instead of a potent pain medication intended for a specific class of patients. . . . This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved.[76]

c. Purdue's 2015 Settlement with the New York Attorney General

319. On August 19, 2015, the New York Attorney General ("NYAG") entered into a settlement agreement with Purdue regarding the company's marketing of opioids.

320. In the settlement agreement, the NYAG noted that, from at least March 2014 to March 2015, the Purdue website, www.inthefaceofpain.com, failed to disclose that doctors who provided testimonials on the site were paid by Purdue. The NYAG concluded that Purdue's

[76] Press Release, U.S. DOJ, Biopharmaceutical Company Cephalon to Pay $425 Million for Off-Label Drug Marketing (Sept. 29, 2008) (available at https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html).

failure to disclose these financial connections misled consumers regarding the objectivity of the testimonials.

321. The settlement agreement stated, in relevant part:

> Purdue maintains an unbranded pain management advocacy website, www.inthefaceofpain.com. From March 2014 to March 2015, the website received a total of 251,648 page views. Much of the video content on www.inthefaceofpain.com is also available on YouTube.
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> * * *
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> Written and video testimonials from several dozen "Advocates," whose faces appear on the website and many of whom are HCPs [health care providers], comprise a central component of the site. For example, Dr. Russell Portenoy, the recipient of almost $4,000 from Purdue for meeting and travel costs, was quoted on the website as follows: "The negative impact of unrelieved pain on the lives of individuals and their families, on the healthcare system, and on society at large is no longer a matter of debate. The unmet needs of millions of patients combine into a major public health concern. Although there have been substantive improvements during the past several decades, the problem remains profound and change will require enormous efforts at many levels. Pressure from patients and the larger public is a key element in creating momentum for change."
>
> Although Purdue created the content on www.inthefaceofpain.com . . . the site creates the impression that it is neutral and unbiased.
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> * * *
>
> ***Purdue's failure to disclose its financial connections with certain Advocates has the potential to mislead consumers by failing to disclose the potential bias of these individuals.***[77]

[Emphasis added.]

322. As part of the settlement, Purdue agreed to make certain disclosures on www.inthefaceofpain.com and its similar websites and to pay a monetary penalty.[78]

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[77] Settlement Agreement between New York Attorney General and Purdue Pharma at 7-8, In the Matter of Purdue Pharma L.P., 2015 N.Y. Op. Att'y Gen. 151 (2015), https:/ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf ("NYAG-Purdue Settlement Agreement").

[78] *Id*. at 15-17.

323. Again, however, Purdue's improper marketing of opioids has continued, following its prior regulatory settlements, all as alleged more fully herein. An October 30, 2017 article in *The New Yorker* states, in pertinent part:

> Purdue has continued to fight aggressively against any measures that might limit the distribution of OxyContin, in a way that calls to mind the gun lobby's resistance to firearm regulations. Confronted with the prospect of modest, commonsense measures that might in any way impinge on the prescribing of painkillers, Purdue and its various allies have responded with alarm, suggesting that such steps will deny law-abiding pain patients access to medicine they desperately need. Mark Sullivan, a psychiatrist at the University of Washington, distilled the argument of Purdue: "Our product isn't dangerous – it's *people* who are dangerous."[79]

[Emphasis in original].

324. Further, according to that article, Purdue has continued to search for new users through the present, both domestically and now increasingly overseas, and in August 2015, even sought to market OxyContin to children as young as 11.[80]

d. Endo's 2016 Settlement with the NYAG

325. On March 1, 2016, the NYAG entered into a settlement agreement with EHS and EPI regarding Endo's marketing and sales of Opana ER.

326. On Endo's website, www.opana.com, Endo claimed, until at least April 2012, that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[81] The NYAG found that Endo had no evidence for that statement.[82]

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79 Patrick Radden Keefe, *The Family That Built an Empire of Pain*, NEW YORKER, Oct. 30, 2017, https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.

80 *Id*.

81 Settlement Agreement between New York Attorney General and Endo, at ¶20, In the Matter of Endo Health Solutions Inc., et al., 2015 N.Y. Op. Att'y Gen. 228 (2016),

327. Endo also provided training materials to its sales representatives stating that addiction to opioids is not common, and that "symptoms of withdrawal do not indicate addiction."[83] The NYAG found that those statements were unwarranted.[84]

328. Endo also trained its sales representatives to distinguish addiction from "pseudoaddiction." ***The NYAG found that "the 'pseudoaddiction' concept has never been empirically validated*** and in fact has been abandoned by some of its proponents," all as alleged above.[85] [Emphasis added.]

329. The NYAG also noted that Endo omitted information about certain studies in its marketing pamphlets distributed to health care providers, and that Endo "omitted . . . adverse events from marketing pamphlets."[86]

330. As part of the NYAG settlement, Endo paid a $200,000 penalty and agreed to refrain from doing the following in New York: (i) "make statements that Opana ER or opioids generally are non-addictive"; (ii) "make statements that most patients who take opioids do not become addicted"; and (iii) "use the term 'pseudoaddiction' in any training or marketing."[87]

e. Mallinckrodt's 2017 Settlement with the DEA and U.S. Attorneys

331. In 2008, the DEA and federal prosecutors launched an investigation into Mallinckrodt, charging that the company ignored red flags by continuing to supply and failing to

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https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf ("NYAG-Endo Settlement Agreement").

82 *Id*.

83 *Id*., ¶22.

84 *Id*.

85 *Id*., ¶23.

86 *Id*., ¶30.

87 *Id*., ¶41.

report suspicious orders for its generic oxycodone between 2008 and 2012.[88] The investigation uncovered that, from 2008 to 2012, Mallinckrodt sent, for example, 500 million tablets of oxycodone into a single state, Florida – "66 percent of all oxycodone sold in the state."[89]

332. Furthermore, despite learning from the DEA that generic opioids seized in a 2009 Tennessee drug sting operation were traceable to one of its distributors, Sunrise Wholesale ("Sunrise"), Mallinckrodt, in the ensuing six weeks, blithely continued to send an additional 2.1 million tablets of oxycodone to Sunrise. In turn, Sunrise sent at least 92,400 oxycodone tablets to a single doctor over an 11-month period, who in one day prescribed 1,000 tablets to a single patient.[90] According to the internal government documents obtained by *The Washington Post*, Mallinckrodt's failure to report could have resulted in "nearly 44,000 federal violations and exposed it to $2.3 billion in fines."[91]

333. During the DEA's investigation, Mallinckrodt sponsored the HDA (known as the Healthcare Distribution Management Association until 2016), an industry-funded organization that represents pharmaceutical distributors.[92] The HDA successfully lobbied for the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (enacted April 19, 2016), which requires the DEA to give pharmacies and distributors a notice of violation and an opportunity to

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88 Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, WASH. POST, Apr. 2, 2017, https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.7ce8c975dd86.

89 *Id.*

90 *Id.*

91 *Id.*

92 *Sponsors: HDA's Annual Circle Sponsors*, HEALTHCARE DISTRIBUTION ALLIANCE, https://www.healthcaredistribution.org/hda-sponsors (last visited June 25, 2018).

comply before withdrawing their licenses. This Act substantially weakened the DEA's ability to regulate manufacturers and wholesalers.[93]

334. In May 2014, Mallinckrodt posted a video titled "Red Flags: Pharmacists Anti-Abuse Video." The video is a thinly veiled attempt to divert responsibility for the opioid epidemic away from manufacturers and wholesalers and toward individual pharmacists. The video was sponsored by the Anti-Diversion Industry Working Group, which is composed of Actavis, Mallinckrodt, and Qualitest (a part of Endo) – all of whom are also missing from the list of those responsible.[94]

335. In April 2017, Mallinckrodt reached an agreement with the DEA and U.S. Attorneys for the Eastern District of Florida and Northern District of New York to pay $35 million to resolve a probe of its distribution of its opioid medications.[95] Mallinckrodt finalized the settlement on July 11, 2017, agreeing to pay $35 million while admitting no wrongdoing.[96]

9. Summary of Marketing Defendants' Unlawful Marketing Claims and Practices

Purdue	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life**

[93] Chris McGreal, *Opioid epidemic: ex-DEA official says Congress is protecting drug makers*, GUARDIAN (Oct. 31, 2016, 9:26 EDT), https://www. theguardian.com/us-news/2016/oct/31/opioid-epidemic-dea-official-congress-big-pharma.

[94] Video: Red Flags, MALLINCKRODT PHARMACEUTICALS, http://www.mallinckrodt.com/corporate-responsibility/red-flags (last visited June 25, 2018).

[95] Linda A. Johnson, *Mallinckrodt to Pay $35M in Deal to End Feds' Opioid Probe*, U.S. NEWS & WORLD REPORT (Apr. 3, 2017, 6:47 PM), https://www.usnews.com/news/business/articles/2017-04-03/mallinckrodt-to-pay-35m-in-deal-to-end-feds-opioid-probe.

[96] Press Release, U.S. Department of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017) (available at https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders).

	a. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The sole reference for the functional improvement claim noted the absence of long-term studies and actually stated: "For functional outcomes, the other analgesics were significantly more effective than were opioids." The *Policymaker's Guide* is still available online. b. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals titled "Pain vignettes," which were case studies featuring patients, each with pain conditions persisting over several months, recommending OxyContin for each. One such patient, "Paul," is described to be a "54-year old writer with osteoarthritis of the hands," and the vignettes imply that an OxyContin prescription will help him work more effectively. c. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids, when used properly, "give [pain patients] a quality of life we deserve." APF distributed 17,200 copies in one year alone, according to its 2007 Annual Report, and the guide currently is available online. d. Purdue sponsored APF's *Exit Wounds* (2009), which taught veterans that opioid medications "increase your level of functioning." *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. e. Purdue sponsored the FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." Purdue also spent over $100,000 to support distribution of the book. f. Purdue's sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life. On information and belief, these deceptive representations were made to practitioners in the MetroHealth area. **Defendant misrepresents the risk of addiction** a. Purdue published a prescriber and law enforcement education

	pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which under the heading "Indications of Possible Drug Abuse" shows pictures of the stigmata of injecting or snorting opioids – skin popping, track marks, and perforated nasal septa. In fact, opioid addicts who resort to these extremes are uncommon; the far more typical reality is patients who become dependent and addicted through oral use. These misrepresentations incorrectly suggest to doctors that as long as they do not observe those signs, they need not worry that their patients are abusing or addicted to opioids. b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which inaccurately claimed that less than 1% of children prescribed opioids will become addicted. This publication is still available online. This publication also asserted that pain is undertreated due to "misconceptions about opioid addiction." c. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which asserted that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. d. A Purdue-funded study with a Purdue co-author claimed that "evidence that the risk of psychological dependence or addiction is low in the absence of a history of substance abuse."[97] The study relied only on the 1980 Porter/Jick Letter to the editor concerning a chart review of hospitalized patients, not patients taking Purdue's long-acting, take-home opioid. Although the term "low" is not defined, the overall presentation suggests the risk is so low as not to be a worry. e. Purdue contracted with AGS to produce a CME, *Pharmacological Management of Persistent Pain in Older Persons*, promoting the 2009 AGS Guidelines. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and the claim is, in fact, untrue. Purdue was aware of the 2009 AGS Guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation that it would seek drug company funding to promote them after their completion. f. APF's *Exit Wounds* (2009), sponsored by Purdue, counseled veterans that "[l]ong experience with opioids shows that people who are not

[97] C. Peter N. Watson, et al., *Controlled-release oxycodone relieves neuropathic pain: a randomized controlled trial in painful diabetic neuropathy*, 105 PAIN 71 (2003).

	predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests it is so low as not to be a worry. g. Purdue's sales representatives told prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore, were less addictive and less likely to be abused. On information and belief, these deceptive representations were made to practitioners in the MetroHealth area. h. Purdue's sales representatives told prescribers that Butrans has a lower abuse potential than other drugs because it was essentially tamperproof and, after a certain point, patients no longer experience a "buzz" from increased dosage. On information and belief, these deceptive representations were made to practitioners in the MetroHealth area. i. Advertisements that Purdue sent to prescribers stated that OxyContin was less likely to be favored by addicts, and therefore, less likely to be abused or diverted, or result in addiction. On information and belief, these deceptive representations were made to practitioners in the MetroHealth area. j. In discussions with prescribers, Purdue's sales representatives omitted discussion of addiction risks related to Purdue's drugs. On information and belief, these material omissions were made in presentations to practitioners in the MetroHealth area. **Defendant deceptively claimed, without scientific support, that the risk of addiction could be avoided or managed** a. Purdue's unbranded website, *In the Face of Pain* (inthefaceofpain.com), states that policies that "restrict[] access to patients with pain who also have a history of substance abuse" and "requiring special government-issued prescription forms for the only medications that are capable of relieving pain that is severe" are "at odds with" best medical practices.[98] b. Purdue sponsored a 2012 CME program, titled *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. This presentation recommended that use of

[98] *See In the Face of Pain Fact Sheet: Protecting Access to Pain Treatment*, PURDUE PHARMA L.P., https://web.archive.org/web/20140423105047/http://www.inthefaceofpain.com:80/content/uploads/2011/12/factsheet_ProtectingAccess.pdf (last updated Apr. 2013).

	screening tools, more frequent refills, and switching opioids could treat a high-risk patient showing signs of potentially addictive behavior. c. Purdue sponsored a 2011 webinar taught by KOL Dr. Lynn Webster, titled *Managing Patients' Opioid Use: Balancing the Need and Risk*. This publication taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing "overuse of prescriptions" and "overdose deaths." d. Purdue's sales representatives told prescribers that screening tools can be used to select patients appropriate for opioid therapy and to manage the risks of addiction. On information and belief, these false representations were made to practitioners in the MetroHealth area. **Defendant falsely stated or suggested the concept of "pseudoaddiction" as patients who only need more opioids, and should be treated as such** a. Purdue published a prescriber and law enforcement education pamphlet in 2011, entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated." b. Purdue distributed to physicians at least as of November 2006, and posted on its unbranded website, *Partners Against Pain*, a pamphlet copyrighted in 2005 and titled *Clinical Issues in Opioid Prescribing*. This pamphlet included a list of conduct, including "illicit drug use and deception," which it defined as indicative of pseudoaddiction or untreated pain. It also states: > Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when ***pain is undertreated***. . . . Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be ***distinguished from true addiction*** in that the behaviors resolve when the pain is effectively treated. [Emphasis added.] c. Purdue sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that certain behaviors, such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction. Purdue also spent over $100,000 to support distribution of the book.

	d. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which states: "Pseudo-addiction describes patient behaviors that may occur when ***pain is undertreated***. . . . Pseudo-addiction can be distinguished from true addiction in that this behavior ceases when pain is effectively treated." [Emphasis added.] **Defendant falsely stated or suggested that withdrawal from opioids was not a problem and that opioids should be prescribed and used without hesitation** a. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not disclose the significant hardships that often accompany cessation of use. b. Purdue's sales representatives told prescribers that the effects of withdrawal from opioid use can be successfully managed. On information and belief, these false representations were made to practitioners in the MetroHealth area. c. Purdue's sales representatives told prescribers that the potential for withdrawal on Butrans was low due to Butrans's low potency and its extended release mechanism. On information and belief, these false representations were made to practitioners in the MetroHealth area. **Defendant suggested that high-dose opioid therapy was safe** a. Purdue's *In the Face of Pain* website, along with initiatives of APF, promoted the notion that if a patient's doctor does not prescribe them what – in their view – is a sufficient dose of opioids, they should find another doctor who will. In so doing, Purdue exerted undue, unfair, and improper influence over prescribers who face pressure to accede to the resulting demands. b. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dose escalations are "sometimes necessary," even indefinitely high ones, which suggested that high-dose opioids are safe and appropriate and did not disclose the risks from high-dose opioids. This publication is still available online. c. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The guide also claimed that some patients "need" a larger dose of the drug, regardless of the dose currently prescribed. This language fails

	to disclose heightened risks at elevated doses. d. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, *Overview of Management Options*, was edited by KOL Dr. Russell Portenoy, among others, and taught that other drugs, but not opioids, are unsafe at high doses. The 2013 version is still available for CME credit. e. Purdue's sales representatives told prescribers that opioids were just as effective for treating patients long-term and omitted any discussion that increased tolerance would require increasing, and increasingly dangerous, doses. On information and belief, these deceptive representations were made to practitioners in the MetroHealth area. **Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs** a. Purdue sponsored APF's *Exit Wounds* (2009), which omits warnings of the risk of interactions between opioids and benzodiazepines that would increase fatality risk. b. Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which advised patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributes 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. c. Purdue sponsored a CME issued by the American Medical Association in 2003, 2007, 2010, and 2013. The CME, *Overview of Management Options*, was edited by KOL Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses. The 2013 version is still available for CME credit. d. Purdue's sales representatives told prescribers that NSAIDs were more toxic than opioids. On information and belief, these false representations were made to practitioners in the MetroHealth area.
Cephalon	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Cephalon sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that relief of pain itself improved patients' functioning. *Responsible Opioid Prescribing* explicitly describes functional

	improvement as the goal of a "long-term therapeutic treatment course." Cephalon also spent $150,000 to purchase copies of the book in bulk and distributed the book through its pain sales force to 10,000 prescribers and 5,000 pharmacists. b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids, when used properly, "give [pain patients] a quality of life we deserve." The *Treatment Options* guide notes that non-steroidal anti-inflammatory drugs have greater risks with prolonged duration of use, but there was no similar warning for opioids. APF distributed 17,200 copies in one year alone, according to its 2007 annual report, and the publication is currently available online. c. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, titled *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that Cephalon's Actiq and Fentora improve patients' quality of life and allow for more activities when taken in conjunction with long-acting opioids. d. Cephalon's sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life. On information and belief, these false representations were made to practitioners in the MetroHealth area. **Defendant misrepresented the risk of addiction** a. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications and REMS: A Patient's Guide*, which claims, among other things, that "patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids." b. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft. c. In discussions with prescribers, Cephalon's sales representatives omitted any discussion of addiction risks related to Cephalon's drugs. On information and belief, these deceptive representations were made to practitioners in the MetroHealth area. **Defendant deceptively claimed without scientific support that the risk of addiction could be avoided or managed**

	a. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that "opioid agreements" between doctors and patients can "ensure that you take the opioid as prescribed." **Defendant falsely stated or suggested the concept of "pseudoaddiction" as patients who only need more opioids, and should be treated as such** a. Cephalon sponsored FSMB's *Responsible Opioid Prescribing* (2007), which taught that certain behaviors, such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction. Cephalon spent $150,000 to purchase copies of the book in bulk and distributed it through its pain sales force to 10,000 prescribers and 5,000 pharmacists. **Defendant suggested that high-dose opioid therapy was safe** a. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of their opioid, regardless of the dose currently prescribed. b. Cephalon sponsored a CME written by KOL Dr. Lynn Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, which was offered online by Medscape, LLC from September 28, 2007 through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids that include aspirin and acetaminophen are less effective to treat breakthrough pain because of dose limitations. c. Cephalon's sales representatives assured prescribers that opioids were safe, even at high doses. On information and belief, these false representations were made to practitioners in the MetroHealth area. **Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs** a. Cephalon sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication attributed 10,000 to 20,000 deaths annually to NSAID overdose. *Treatment Options* also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids. b. Cephalon's sales representatives told prescribers that NSAIDs were

	more toxic than Cephalon's opioids. On information and belief, these false representations were made to practitioners in the MetroHealth area.
Janssen	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Janssen sponsored a patient education guide, titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. On the cover, this guide features a man playing golf and lists examples of expected functional improvement from opioids, such as sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. The guide states as a "fact" that "opioids may make it *easier* for people to live normally" [emphasis in the original]. The myth/fact structure implies authoritative backing for the claim that does not exist. The targeting of older adults also ignores heightened opioid risks in this population. b. Janssen sponsored, developed, and approved content of a website, *Let's Talk Pain* in 2009, acting in conjunction with APF, AAPM, and American Society of Pain Management Nursing, whose participation in *Let's Talk Pain* Janssen financed and orchestrated. This website featured an interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to "continue to function," inaccurately implying that the patient's experience would be representative. c. Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that opioid medications "*increase* your level of functioning" [emphasis in the original]. *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. d. Janssen's sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work. On information and belief, these false representations were made to practitioners in the MetroHealth area. **Defendant misrepresents the risk of addiction** a. Janssen sponsored a patient education guide, titled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide

	described a "myth" that opioids are addictive and asserts, as fact, that "[m]any studies show that opioids are ***rarely*** addictive when used properly for the management of chronic pain." [Emphasis added.] Although the term "rarely" is not defined, the overall presentation suggests the risk is so low as not to be a worry. The language also implies that as long as a prescription is given, opioid use is not a problem. b. Janssen contracted with AGS to produce a CME, *Pharmacological Management of Persistent Pain in Older Persons*, promoting the 2009 AGS Guidelines. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." The study supporting this assertion does not analyze addiction rates by age and, as already noted, addiction remains a significant risk for elderly patients. Janssen was aware of the 2009 AGS Guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation that it would seek drug company funding to promote them after their completion. c. Janssen provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests the risk is so low as not to be a worry. d. Janssen currently runs a website, *PrescribeResponsibly.com* (last modified July 2, 2015), which claims that concerns about opioid addiction are "overstated." e. A June 2009 Nucynta training module warns Janssen's sales force that physicians are reluctant to prescribe controlled substances like Nucynta, but this reluctance is unfounded because "the risks . . . are much smaller than commonly believed." f. Janssen's sales representatives told prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore, were less addictive and less likely to be abused. On information and belief, these deceptive representations were made to practitioners in the MetroHealth area. g. Janssen's sales representatives told prescribers that Nucynta and Nucynta ER were "not opioids," implying that the risks of addiction and other adverse outcomes associated with opioids were not applicable to Janssen's drugs. In truth, however, as set out in Nucynta's FDA-mandated label, Nucynta "contains tapentadol, an opioid agonist and

	Schedule II substance with abuse liability similar to other opioid agonists, legal or illicit." On information and belief, these false representations were made to practitioners in the MetroHealth area. h. Janssen's sales representatives told prescribers that Nucynta's unique properties eliminated the risk of addiction associated with the drug. On information and belief, these false representations were made to practitioners in the MetroHealth area. i. In discussions with prescribers, Janssen's sales representatives omitted discussion of addiction risks related to Janssen's drugs. On information and belief, these deceptive representations were made to practitioners in the MetroHealth area. **Defendant falsely stated or suggested the concept of "pseudoaddiction" as patients who only need more opioids, and should be treated as such** a. Janssen's website, *Let's Talk Pain*, stated from 2009 through 2011 that "pseudoaddiction . . . refers to patient behaviors that may occur when ***pain is under-treated***" and "[p]seudoaddiction is ***different from true addiction*** because such behaviors can be resolved with effective pain management." [Emphasis added.] **Defendant falsely stated or suggested that withdrawal from opioids was not a problem and that opioids should be prescribed and used without hesitation** a. A Janssen PowerPoint presentation used for training its sales representatives, titled "Selling Nucynta ER," indicates that the "low incidence of withdrawal symptoms" is a "core message" for its sales force. This message is repeated in numerous Janssen training materials between 2009 and 2011. The studies supporting this claim did not describe withdrawal symptoms in patients taking Nucynta ER beyond 90 days or at high doses and would therefore not be representative of withdrawal symptoms in the chronic pain population. Patients on opioid therapy long-term, and at high doses, will have a harder time discontinuing the drugs and are more likely to experience withdrawal symptoms. In addition, in claiming a low rate of withdrawal symptoms, Janssen relied upon a study that only began tracking withdrawal symptoms in patients two to four days after discontinuing opioid use, when Janssen knew, or should have known, that these symptoms peak earlier than that for most patients. Relying on data after that initial window painted a misleading picture of the likelihood and severity of withdrawal associated with chronic opioid therapy. Janssen also knew, or should have known, that the patients involved in the study were not

	on the drug long enough to develop rates of withdrawal symptoms comparable to rates of withdrawal suffered by patients who use opioids for chronic pain – the use for which Janssen promoted Nucynta ER. b. Janssen's sales representatives told prescribers that patients on Janssen's drugs were less susceptible to withdrawal than those on other opioids. On information and belief, these false representations were made to practitioners in the MetroHealth area. **Defendant suggested that high-dose opioid therapy was safe** a. Janssen sponsored a patient education guide, entitled *Finding Relief: Pain Management for Older Adults* (2009), which its personnel reviewed and approved and its sales force distributed. This guide listed dose limitations as "disadvantages" of other pain medicines, but omitted any discussion of risks of increased doses from opioids. The publication also falsely claimed that it is a "myth" that "opioid doses have to be bigger over time."
Endo	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Endo sponsored a website, painknowledge.com, through APF and the National Initiative of Pain Control ("NIPC"), which claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Endo continued to provide funding for this website through 2012 and closely tracked unique visitors to it. b. A CME sponsored by Endo, titled *Persistent Pain in the Older Patient*, taught that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." c. Endo distributed handouts to prescribers that claimed that use of Opana ER to treat chronic pain would allow patients to perform work as a chef. This flyer also emphasized Opana ER's indication without including equally prominent disclosure of the "moderate to severe pain" qualification.[99] d. Endo's sales force distributed FSMB's *Responsible Opioid Prescribing* (2007). This book taught that relief of pain itself improved

[99] FDA regulations require that warnings or limitations be given equal prominence in disclosure, and failure to do so constitutes misbranding of the product. 21 C.F.R. § 202.1(e)(3); see also 21 U.S.C. §331(a).

	patients' function. *Responsible Opioid Prescribing* explicitly describes functional improvement as the goal of a "long-term therapeutic treatment course." e. Endo provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that opioid medications "*increase* your level of functioning" [emphasis in the original]. *Exit Wounds* also omits warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. Benzodiazepines are frequently prescribed to veterans diagnosed with post-traumatic stress disorder. f. Endo's sales representatives told prescribers that opioids would increase patients' ability to function and improve their quality of life by helping them become more physically active and return to work. On information and belief, these false representations were made to practitioners in the MetroHealth area. **Defendant misrepresented the risk of addiction** a. Endo trained its sales force in 2012 that use of long-acting opioids resulted in increased patient compliance, without any supporting evidence. b. Endo's advertisements for the 2012 reformulation of Opana ER claimed it was ***designed to be crush resistant***, in a way that conveyed that it was less likely to be abused. This claim was false; the FDA warned in a May 10, 2013 letter that there was no evidence that Endo's design "would provide a reduction in oral, intranasal or intravenous abuse" and Endo's "postmarketing data submitted are insufficient to support any conclusion about the overall or route-specific rates of abuse." Further, Endo instructed its sales representatives to repeat this claim about "design," with the intention of conveying Opana ER was less subject to abuse. c. Endo sponsored a website, painknowledge.com, through APF and NIPC, which claimed in 2009 that: "[p]eople who take opioids as prescribed usually do not become addicted." Although the term "usually" is not defined, the overall presentation suggests the risk is so low as not to be a worry. The language also implies that as long as a prescription is given, opioid use will not become problematic. Endo continued to provide funding for this website through 2012 and closely tracked unique visitors to it. d. Endo sponsored a website, PainAction.com, which stated "Did you know? Most chronic pain patients do not become addicted to the opioid

	medications that are prescribed for them." e. Endo sponsored CMEs published by APF and NIPC, of which Endo was the sole funder, titled *Persistent Pain in the Older Adult* and *Persistent Pain in the Older Patient*. These CMEs claimed that opioids used by elderly patients present "possibly less potential for abuse than in younger patients[,]" which statement lacks evidentiary support and deceptively minimizes the risk of addiction for elderly patients. f. Endo distributed an education pamphlet with the Endo logo, titled *Living with Someone with Chronic Pain*, which inaccurately minimized the risk of addiction: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." g. Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. It claimed that "[a]ddicts take opioids for other reasons [than pain relief], such as unbearable emotional problems." This implies that pain patients prescribed opioids will not become addicted, which is unsupported and untrue. h. Endo contracted with AGS to produce a CME, *Pharmacological Management of Persistent Pain in Older Persons*, promoting the 2009 AGS Guidelines. These guidelines falsely claim that "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse." None of the references in the guidelines corroborates the claim that elderly patients are less likely to become addicted to opioids, and there is no such evidence. Endo was aware of the 2009 AGS Guidelines' content when it agreed to provide this funding, and AGS drafted the guidelines with the expectation it would seek drug company funding to promote them after their completion. i. Endo's sales representatives told prescribers that its drugs were "steady state," the implication of which was that they did not produce a rush or euphoric effect, and therefore were less addictive and less likely to be abused. On information and belief, these false representations were made to practitioners in the MetroHealth area. j. Endo provided grants to APF to distribute *Exit Wounds* (2009) to veterans, which taught that "[l]ong experience with opioids shows that people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." Although the term "very unlikely" is not defined, the overall presentation suggests that the risk is so low as not to be a worry. k. In discussions with prescribers, Endo's sales representatives omitted

	discussion of addiction risks related to Endo's drugs. On information and belief, these material omissions were made in representations to practitioners in the MetroHealth area. **Defendant deceptively claimed, without scientific support, that the risk of addiction could be avoided or managed** a. An Endo-supported publication, titled *Pain Management Dilemmas in Primary Care: Use of Opioids*, recommended screening patients using tools like the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain and advised that patients at high risk of addiction could safely (*e.g.*, without becoming addicted) receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts. **Defendant falsely stated or suggested the concept of "pseudoaddiction" as patients who only need more opioids, and should be treated as such** a. Endo distributed copies of a book by KOL Dr. Lynn Webster, entitled *Avoiding Opioid Abuse While Managing Pain* (2007). Endo's internal planning documents describe the purpose of distributing this book as to "[i]ncrease the breadth and depth of the Opana ER prescriber base." The book claims that, when faced with signs of aberrant behavior, the doctor should regard it as pseudoaddiction and thus, increasing the dose ***in most cases . . . should be the clinician's first response***." [Emphasis added.] b. Endo spent $246,620 to buy copies of FSMB's *Responsible Opioid Prescribing* (2007), which was distributed by Endo's sales force. This book asserted that certain behaviors, such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of "pseudoaddiction." **Defendant falsely stated or suggested that withdrawal from opioids was not a problem and that opioids should be prescribed and used without hesitation** a. A CME sponsored by Endo, titled *Persistent Pain in the Older Adult*, taught that withdrawal symptoms can be avoided entirely by tapering the dose by 10-20% per day for ten days. **Defendant suggested that high-dose opioid therapy was safe** a. Endo sponsored a website, painknowledge.com, through APF and

	NIPC, which claimed in 2009 that opioids may be increased until "you are on the right dose of medication for your pain," and once that occurs, further dose increases would not occur. Endo funded the site, which was a part of Endo's marketing plan, and tracked visitors to it. b. Endo distributed a patient education pamphlet edited by KOL Dr. Russell Portenoy, titled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked: "If I take the opioid now, will it work later when I really need it?" The response was: "The dose can be increased[.] . . . You won't 'run out' of pain relief." **Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs** a. Endo distributed a "case study" to prescribers, titled *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*. The study cites an example, meant to be representative, of a patient "with a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" (over eight years), and recommends treating with opioids instead. b. Endo sponsored a website, painknowledge.com, through APF and NIPC, which contained a flyer called "Pain: Opioid Therapy." This publication included a list of adverse effects from opioids that omitted significant adverse effects like hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death. Endo continued to provide funding for this website through 2012 and closely tracked unique visitors to it. c. Endo provided grants to APF to distribute *Exit Wounds* (2009), which omitted warnings of the risk of interactions between opioids and benzodiazepines, which would increase fatality risk. *Exit Wounds* also contained a lengthy discussion of the dangers of using alcohol to treat chronic pain but did not disclose dangers of mixing alcohol and opioids. d. Endo sales representatives told prescribers that NSAIDs were more toxic than opioids. On information and belief, these false representations were made to practitioners in the MetroHealth area.
Actavis	**Falsehood that scientific evidence supports the long-term use of opioids to improve patients' function and quality of life** a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct prescribers that "***most*** chronic benign pain patients do have ***markedly improved ability to function*** when maintained on chronic opioid therapy." [Emphasis added.]

	b. Documents from a 2010 sales training indicate that Actavis trained its sales force that increasing and restoring function is an expected outcome of chronic Kadian therapy, including physical, social, vocational, and recreational function. c. Actavis distributed a product advertisement that claimed that use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and "cause patients to enjoy their lives." The FDA warned Actavis such claims were misleading, writing: "We are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect the drug has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in an overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[100] d. Actavis's sales representatives told prescribers that prescribing Actavis's opioids would improve their patients' ability to function and improve their quality of life. On information and belief, these false representations were made to practitioners in the MetroHealth area. **Defendant misrepresented the risk of addiction** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that long-acting opioids were less likely to produce addiction than short-acting opioids, although there is no evidence that either form of opioid is less addictive or that any opioids can be taken long-term without the risk of addiction. b. Actavis's sales representatives told prescribers that Kadian was "steady state" and had extended release mechanisms, the implication of which was that it did not produce a rush or euphoric effect, and therefore was less addictive and less likely to be abused. On information and belief, these false representations were made to practitioners in the MetroHealth area. c. Actavis's sales representatives told prescribers that the contents of Kadian could not be dissolved in water if the capsule was opened, implying that Kadian was less likely to be abused – and thereby less addictive – than other opioids. On information and belief, these deceptive representations were made to practitioners in the MetroHealth area.

[100] Abrams, *supra* n.72.

	d. In discussions with prescribers, Actavis's sales representatives omitted any discussion of addiction risks related to Actavis's drugs. On information and belief, these material omissions were made in presentations to practitioners in the MetroHealth area. **Defendant deceptively claimed, without scientific support, that the risk of addiction could be avoided or managed** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that prescribers can use risk screening tools to limit the development of addiction. **Defendant falsely stated or suggested the concept of "pseudoaddiction" as patients who only need more opioids, and should be treated as such** a. Documents from a 2010 sales training indicate that Actavis trained its sales force to instruct physicians that aberrant behaviors, like self-escalation of doses, constituted "pseudoaddiction." **Defendant falsely stated or suggested that withdrawal from opioids was not a problem and that opioids should be prescribed and used without hesitation** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that discontinuing opioid therapy can be handled "simply" and at home. Actavis's sales representative training claimed opioid withdrawal would take only a week, even for addicted patients. **Defendant suggested that high-dose opioid therapy was safe** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that "individualization" of opioid therapy depended on increasing doses "until patient reports adequate analgesia" and to "set dose levels on [the] basis of patient need, not on [a] predetermined maximal dose." Actavis further counseled its sales representatives that the reasons some physicians had for not increasing doses indefinitely were simply a matter of physician "comfort level," which could be overcome or used as a tool to induce them to switch to Actavis's opioid, Kadian. **Defendant deceptively omitted the risks of opioids, including in comparison to NSAIDs** a. Documents from a 2010 sales training indicate that Actavis trained its sales force that the ability to escalate doses during long-term opioid therapy, without hitting a dose ceiling, made opioid use safer than other

	forms of therapy that had defined maximum doses, such as acetaminophen or NSAIDs. b. Actavis also trained physician-speakers that "maintenance therapy with opioids can be safer than long-term use of other analgesics," including NSAIDs, in older persons. c. Actavis's sales representatives told prescribers that NSAIDs were more toxic than opioids. On information and belief, these false representations were made to practitioners in the MetroHealth area.
Mallinckrodt	**Defendant Mallinckrodt funded false publications and presentations.** a. In 2010, Mallinckrodt sponsored an initiative called "Collaborating and Acting Responsibly to Ensure Safety" ("C.A.R.E.S.") through which it published and promoted the book "Defeat Chronic Pain Now!" that is aimed at chronic pain patients and offers to provide patients with information about "new medications . . . that can be used to rewire your body for pain relief." The book is still available for sale and available online at www.defeatchronicpainnow.com. b. Until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as "a noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices."[101] Among other content, the website included a handout, titled "Oxycodone Safety Handout for Patients," which advised practitioners that: "Patients' fears of opioid addiction should be dispelled."[102] c. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb, the current commissioner of the FDA, $22,500 for a speech in London shortly after the U.S. presidential election.[103] Dr. Gottlieb has also received money from the Healthcare Distribution Alliance ("HDA"), an industry-funded

[101] *Pain Treatment Topics*, PAIN-TOPICS.ORG, https://web.archive.org/web/20070104235709/http://www.pain-topics.org:80/ (last updated Jan. 3, 2007).

[102] Lee A. Kral, PharmD & Stewart B. Leavitt, MA, *Oxycodone Safety Handout for Patients*, PAIN-TOPICS.ORG (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

[103] Lee Fang, *Donald Trump's Pick to Oversee Big Pharma Is Addicted to Opioid-Industry Cash*, INTERCEPT (Apr. 4, 2017, 2:15 PM), https://theintercept.com/2017/04/04/scott-gottlieb-opioid/.

	organization that pushes the agenda of large pharmaceutical wholesalers, and he has often criticized efforts aimed at regulating the pharmaceutical opioid market.[104] **Defendant misrepresents the risk of addiction** a. "Defeat Chronic Pain Now!" advises laypeople who are considering taking opioid drugs that "[o]nly rarely does opioid medication cause true addiction."[105] b. "Oxycodone Safety Handout for Patients" included false and misleading statements concerning the risk of addiction associated with prescription opioids: > Will you become dependent on or addicted to oxycodone? > • After a while, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop. > • This is not the same as addiction, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.[106] **Defendant deceptively claimed, without scientific support, that the risk of addiction could be avoided or managed.** a. "Defeat Chronic Pain Now!" states that the issue of tolerance is "overblown," because "[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance." In response to a hypothetical question from a chronic back pain patient, who expresses a fear of becoming addicted, the book advises that "[i]t is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1)

104 *Id.*

105 Galer, *supra* n.50.

106 Kral, *supra* n.102.

	he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain." **Defendant falsely stated or suggested the concept of "pseudoaddiction" as patients who only need more opioids, and should be treated as such.** a. The FAQ section of Pain-Topics.org contained the following false and misleading information downplaying the dangers of prescription opioid use: > **Pseudoaddiction** – has been used to describe aberrant patient behaviors that may occur when pain is undertreated (AAPM 2001). Although this diagnosis is not supported by rigorous investigation, it has been widely observed that patients with unrelieved pain may become very focused on obtaining opioid medications, and may be erroneously perceived as "drug seeking." Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated. Along with this, two related phenomena have been described in the literature (Alford, et al. 2006): > > **Therapeutic dependence** – sometimes patients exhibit what is considered drug-seeking because they fear the reemergence of pain and/or withdrawal symptoms from lack of adequate medication; their ongoing quest for more analgesics is in the hopes of insuring a tolerable level of comfort. > > **Pseudo-opioid-resistance** – other patients, with adequate pain control, may continue to report pain or exaggerate its presence, as if their opioid analgesics are not working, to prevent reductions in their currently effective doses of medication. > Patient anxieties about receiving inadequate pain control can be profound, resulting in demanding or aggressive behaviors that are misunderstood by healthcare practitioners and ultimately detract from the provision of adequate pain relief.[107]

[107] *FAQs*, PAIN-TOPICS.ORG, https://web.archive.org/web/20080821191924/http://www.paintopics.org/faqs/index1.php (last updated Jan. 8, 2008).

	b. Defendant's document, "Commonsense Oxycodone Prescribing & Safety," falsely suggests that generic oxycodone is less prone to abuse and diversion than branded oxycodone: "Anecdotally, it has been observed that generic versions of popularly abused opioids usually are less appealing; persons buying drugs for illicit purposes prefer brand names because they are more recognizable and the generics have a lower value 'on the street,' which also makes them less alluring for drug dealers."[108] **Defendant misbranded and marketed an unapproved drug** a. On March 30, 2009, Mallinckrodt received a letter from the FDA stating that Mallinckrodt was found to have been marketing an unapproved new drug, morphine sulfate concentrate oral solution 20 mg/ml, in violation of 21 U.S.C. §§331(d), 355(a). Mallinckrodt had been marketing this unapproved formulation since 2005. b. The letter also stated that its unapproved morphine formulation was misbranded under 21 U.S.C. §352(f)(1) because the conditions it was intended to treat were not amenable to self-diagnosis and treatment. Adequate directions for such use, therefore, could not be written. As a result, introduction or delivery for introduction into interstate commerce of its unapproved morphine formulation violated 21 U.S.C. §§331(a) and (d).
Insys	Defendant's sales representatives falsely told prescribers in the MetroHealth area that withdrawal from opioids was not a problem and prescribing or using opioids should be without hesitation. Defendant's sales representatives falsely told prescribers in the MetroHealth area that high-dose opioid therapy was safe and advocated starting patients at a higher than approved dosage. Defendant's sales representatives, in false representations to prescribers in the MetroHealth area, deceptively omitted the risks of opioids, including in comparison to NSAIDs Defendant created a system of insurance reimbursement to get its prescriptions approved that was based on fraud, such as advising the insurance companies that they were calling from the physician's office or falsely advising the insurance companies that the patient had cancer

[108] Lee A. Kral, PharmD, BCPS, *Commonsense Oxycodone Prescribing & Safety*, PAIN-TOPICS.ORG (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneRxSafety.pdf.

	when (s)he did not.

D. Defendants Are Estopped from Asserting Statute of Limitations or Laches Defenses

1. The Marketing Defendants Fraudulently Concealed Their Misconduct

336. The Marketing Defendants, both individually and collectively, made, promoted, and handsomely profited from their misrepresentations and material omissions about the risks and benefits of opioids for chronic pain, even though they knew that their misrepresentations and material omissions were false and deceptive. The long-held medical view, along with research and clinical experience prior to the commencement of the Marketing Defendants' campaign of disinformation, established that opioids are highly addictive and responsible for a long list of serious adverse outcomes, including death. Upon information and belief, the FDA warned Defendants of the questionable basis of chronic long-term use of opioids, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the devastating harm from long-term opioid use. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Defendants' misrepresentations.

337. Endo and Purdue have recently entered into agreements in the State of New York prohibiting them from making some of the same misrepresentations described in this Complaint.

338. At all times relevant to this Complaint, the Marketing Defendants took steps that were designed to, and did in fact, fraudulently conceal their deceptive marketing and unlawful conduct. For example, the Marketing Defendants disguised their role in the deceptive marketing of long-term opioid therapy by secretly funding and working through third parties, such as Front Groups and KOLs. The Marketing Defendants never disclosed their role in shaping, editing, and

approving the content of information and materials disseminated by these third parties. They did not reveal that CMEs on pain management had been infiltrated by persons that were being paid to espouse the deceptive position of the Marketing Defendants that opioids were a safe modality for the treatment of chronic pain, and to suppress the presentation of any other views.

339. The Marketing Defendants, other than Insys, ran websites with generic names, such as painknowledge.com, that were actually funded, in substantial part, by the Marketing Defendants.

340. The Marketing Defendants manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. For example, the Marketing Defendants, other than Insys, distorted the import of the Porter/Jick Letter to the NEJM (*see supra* ¶¶178-185). The Marketing Defendants, other than Insys, invented "pseudoaddiction" and promoted it to an unsuspecting medical community. *Supra* ¶¶163-167. The Marketing Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. *See supra* ¶¶158-162. The Marketing Defendants spent tens of millions of dollars over a period of years on a misinformation campaign and so permeated the avenues where information was disseminated to physicians and the medical community that it was difficult, if not impossible, for medical professionals to detect the truth.

341. The Marketing Defendants, other than Insys, also promoted the false information regarding the relative safety of chronic opioid use directly to the public, especially directing their messages to the elderly and veterans (*supra* ¶¶266-281). The deception was so widespread that it was difficult for the public to learn the true risk of opioids.

342. It was difficult, if not impossible, for Plaintiff to detect the harm being perpetrated on the health of individuals within its service area and the public health of Cuyahoga County as a whole, until the explosion of opioid overdoses began to hit its emergency room. By virtue of Defendants secreting the existence of their industry-wide scheme, Plaintiff did not and could not have known of the harm that was being inflicted on it and the community whose public health it serves, nor could it have acquired such knowledge through the exercise of reasonable diligence.

2. The Statute of Limitations and Laches Doctrine Do Not Apply Here

343. The medical community, patients, their families, the State of Ohio, and Plaintiff were duped by the Marketing Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in Ohio and the area served by MetroHealth.

344. All Defendants intended that their actions and omissions would be relied upon, including by MetroHealth. MetroHealth and its clinical staff did not know, and did not have the means to know, that the Defendants were misrepresenting the true risks of their products because of the pervasive manner in which Defendants singularly, as well as collectively, did not reveal the true risks of opioids and affirmatively made misstatements minimizing their risks.

345. Plaintiff reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law.

346. The purposes of the statute of limitations period and laches doctrine are satisfied in this case because Defendants cannot claim prejudice where Plaintiff filed suit promptly upon discovering the facts essential to its claims, as described herein, which Defendants knowingly concealed. Plaintiff did not and could not have previously known through the exercise of reasonable diligence of its causes of action as a result of Defendants' conduct.

347. To this day, Defendants continue their deception to avoid compliance with their legal obligations by falsely characterizing the opioid epidemic in Plaintiff's community, as well as the nation, as one of "abuse." In truth, as the Defendants have known for years, the proximate cause of the epidemic is the "use" of opioids – which have been described as "heroin pills" – for long-term pain treatment, which use was always highly dangerous, medically contraindicated, and likely to cause addiction in the widespread manner exactly as it has occurred.

348. Plaintiff continues to suffer harm from the public nuisance created by the unlawful actions by the Defendants and, until the nuisance is abated, the harm to Plaintiff will continue for the foreseeable future.

E. Damages to MetroHealth

349. As a foreseeable, direct, and proximate result of the unlawful conduct of the Defendants, along with those of the third-party Front Groups and KOLs that are assisted and controlled by the Marketing Defendants, the patient population of MetroHealth, along with many other communities in the United States, has been subjected to devastating public health epidemics of addiction and overdose.

350. As discussed *supra* ¶¶114-121, it is well-recognized and well-established biology that, once a person becomes addicted to opioid stimulation of opioid receptors in his or her brain, that person is compelled to continue to crave and seek out that stimulation, even if the original prescription drug that began the addiction is no longer available, either because it is too expensive or because prescription opioids have become more restricted. Absent treatment, which is often not effective, the opioid-addicted person will use illicit opioids, such as heroin,

fentanyl, or a combination of those opioids, if they are available. People who are addicted to prescription opioid painkillers are 40 times more likely to become addicted to heroin.[109]

1. Nuisance Abatement Expenditures

351. MetroHealth has been forced to spend extraordinary funds each year in its efforts to combat the public nuisance created by Defendants. MetroHealth has incurred, and continues to incur, costs related to treating persons affected by opioid addiction, including but not limited to: increased hospitalizations and longer stays in the hospital for treatment of opioid addiction, as well as unrelated illnesses that involve more complex treatment due to the combination of the illness plus opioid addiction; managing escalated overdose rates; prevention efforts in the community; education efforts in the community and within MetroHealth; neo-natal care for addicted newborns; and maternal care. MetroHealth's efforts extend not only to afflicted patients. Due to need, MetroHealth has already set up, and is working to expand, a wrap-around service for the family members (including infants and young children) who are negatively affected by the addiction of a family member.

352. The issue of trying to "get ahead of the epidemic," or at least staunch its devastation, is a number one priority for MetroHealth. MetroHealth, its departments, medical staff, and other employees, in partnership with community groups, are working tirelessly, 24 hours a day, seven days a week trying to curb this epidemic and its destructive wake.

353. Many of the services that MetroHealth is now forced to provide, oversee, and/or coordinate are not traditionally considered to be county hospital services, but have become necessary for MetroHealth to undertake in an effort to protect its community's lives, health, and

[109] *See Today's Heroin Epidemic*, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).

the well-being from the devastating effects of the opioid epidemic created and fueled by Defendants.

354. Among the expenditures incurred and the services rendered, which will continue to be needed and expanded for the foreseeable future by MetroHealth in an effort to abate the public nuisance, are the following:

(a) Costs for providing healthcare and additional therapeutic, prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdose treatment and prevention;

(b) Costs for providing healthcare and additional therapeutic, prescription drug purchases, and other treatments for patients suffering from injection-related diseases including hepatitis C, heart valve infections, and skin infections;

(c) Costs for providing healthcare and additional therapeutic, prescription drug purchases, and other treatments for patients suffering anoxic brain injury from an opioid overdose;

(d) Costs of training and re-training physicians, nurse practitioners, physicians assistants, and other hospital personnel in the safe and proper methods for prescribing opioid pain medication and treatment of opioid overdoses and addiction;

(e) Costs associated with data enhancements on MetroHealth's "Epic" software program, which holds medical records and is used by all clinicians employed by MetroHealth, to ensure that any opioid prescription contains numerous protocols to enhance the safety of the patient (*infra* ¶411).

(f) Costs associated with providing addicted individuals, their family members, and others in the community serviced by MetroHealth with opioid antagonists, such as naloxone, used to block opioid overdoses;

(g) Costs associated with locating individuals described above, training them in the use of the equipment, and continually re-supplying such individuals;

(h) Costs for providing mental health services, treatment, rehabilitation services, and social services to victims of the opioid epidemic and their families; and

(i) Costs for providing treatment of infants born with opioid-related medical conditions or born dependent on opioids due to drug use by his/her mother during pregnancy.

355. The above list is only illustrative and does not include every category of expense, investment, and necessary service that has been, and will continue to be, incurred by MetroHealth as a direct and proximate result of Defendants' wrongdoing.

2. Defendants' Excessive Opioid Supply Sets the Stage for Plaintiff's Injuries

356. As noted above, the Marketing Defendants unlawfully, by their misrepresentations, fraud, violations of various statutes, and common law negligence, orchestrated a scheme to pump millions and millions of prescription opioids, otherwise known as "heroin pills," into Ohio in general, and MetroHealth and its surrounding environs in particular.

357. In August 2016, then-U.S. Surgeon General, Vivek Murthy, published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . .

[m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."

358. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain, therefore, are at much higher risk of overdose. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

359. Ohio has the 12th highest opioid prescription rate in the country, with approximately 100.1 opioid prescriptions written for every 100 persons in Ohio. [110] As reported by the Ohio Department of Health, there were over 4.4 billion solid doses (excluding liquid doses) of prescription opioids dispensed in Ohio between 2011 and 2016.[111]

360. Opioid prescription rates in Cuyahoga County tracked (or exceeded) the State's rates. For instance, in 2012, the prescribing rate for opioids in Cuyahoga County was 76.2 prescriptions per hundred people.

361. A database known as the "Automation of Reports and Consolidated Orders System" ("ARCOS") was set up under the 1970 Controlled Substances Act. ARCOS is a comprehensive reporting system that shows the flow of every controlled substance from its point of manufacture, through the distributor, and on to the Retail End User. The following chart is

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[110] *See* Leonard J. Paulozzi, M.D., et al., *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines – United States, 2012*, 63 MORBIDITY AND MORTALITY WKLY. REP. 563 (2014). The combination of hydrocodone, oxycodone, and benzodiazepines is referred to as the "holy trinity" and significantly increases the risk of harm to those that abuse prescription pills.

[111] 2016 Ohio Drug Overdose Data, *supra* n.14.

derived from the ARCOS database and shows the increases in the volumes of various opioid-based drugs distributed in Cuyahoga County to fill prescriptions from 2006 to 2017:

ARCOS DATABASE – CUYAHOGA COUNTY, OH

Drug Name/Code	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Buprenorphine/9064	1,885.93	2,627.27	3,849.72	5,143.79	5,941.84	6,240.23	6,832.71	7,939.37	8,966.20	9,798.98	11,113.66	12,346.51
Fentanyl Base/9801	1,330.77	1,380.30	1,377.66	1,351.55	1,397.52	1,323.08	1,231.76	1,100.15	1,154.41	989.33	855.2	699.44
Hydrocodone/9193	54,758.11	64,498.96	69,450	75,680.80	75,493.74	78,632.17	75,179.71	71,159.48	66,993.01	55,681.31	48,733.90	40,811.98
Hydromorphone/9150	3,533.98	4,111.21	4,832.87	5,838.85	5,282.95	6,470.75	6,842.93	6,470.94	5,673.47	4,931.94	4,527.52	4,324.39
Morphine/9300	51,651.33	54,193.63	55,832.54	61,832.23	58,282.08	56,458.59	56,005.64	49,263.63	46,893.83	44,726.19	40,252.11	34,337.83
Oxycodone/9143	146,197.62	164,626.73	182,195.79	210,312.95	225,934.74	221,482.33	214,296.68	200,322.07	192,516.61	187,447.79	173,881.90	148,636.79
Oxymorphone/9652	266.31	1,328.77	2,412.68	3,766.67	5,067.13	12,565.68	4,698.07	2,451.33	1,786.04	1,739.81	1,572.80	1,209.78
Tapentadol/9780	---	---	---	4,284.75	15,110	23,070	24,164.50	22,369.50	22,219	19,944.50	19,734	15,552

362. To put this in perspective, during 2016 there were 76 opioid prescriptions written for every 100 individuals that reside within Cuyahoga County. And, despite efforts by local and state officials, and spearheaded by MetroHealth itself, to curb the crisis and limit the number of pills in the County, the prescribing rate remained above 61% in 2016. This conduct caused a public health crisis and public nuisance that now is laid at the feet of MetroHealth.

363. In addition, the opioid epidemic has evolved to include heroin, fentanyl, and carfentanil in the crisis impacting MetroHealth. As noted above, fentanyl and carfentanil are highly lethal.

364. Adding to the danger, in some instances fentanyl has been made to look exactly like oxycodone tablets. For example, in February 2016, federal agents in suburban Cleveland, Ohio seized 900 fentanyl pills that were marked like the 30 milligram oxycodone tablets manufactured by Defendant Mallinckrodt including the signature "M" imprint and light blue color.[112] The Cuyahoga County Medical Examiner has explained that such lookalike pills are

[112] Associated Press, *Mislabeled Painkillers "a Fatal Overdose Waiting to Happen"*, CBS NEWS (Feb. 29, 2016, 10:46am), https://www.cbsnews.com/news/mislabeled-painkillers-a-fatal-overdose-waiting-to-happen/.

likely to blame for some of the fentanyl deaths in the County.[113] The opioid prescription rates in MetroHealth exceeded, and still greatly exceed, any legitimate medical purpose and were driven by the deceptive campaign of Marketing Defendants.

365. The opioid prescription rates within Cuyahoga County exceeded, and still greatly exceed, appropriate medical purposes and were driven by the deceptive campaign of Marketing Defendants.

366. But for the misleading information disseminated by Marketing Defendants, providers in the MetroHealth area would not have begun prescribing opioids as a regular treatment modality for everyday pain.

3. Overdose-Related Deaths

a. State of Ohio

367. As a foreseeable result of increases in opioid drug prescriptions in a community, there follows, as night follows day, increases in overdoses, deaths, and addictions.

368. Ohio has been experiencing a heroin overdose outbreak. In fact, scientific studies support the finding that increases in opioid overdoses in general (as well as fatal opioid overdoses) in a community follow, by several years, the peak number of prescription opioids in that community.

369. As a recent report from Ohio State University summarizes, "[o]pioid addiction, abuse, and overdose deaths have become the most pressing public health issue facing Ohio." The rapid rise in overdose deaths in Ohio and the United States, as a whole, is unprecedented.

370. Indeed, the observation concerning the increase in overdose deaths following an increase in opioid prescriptions is borne out in the State of Ohio. Notably, from 2000 to 2015,

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113 *Id.*

Ohio experienced a more than 642% increase in drug overdose deaths, a startling statistic driven largely by overdoses from prescription drugs. More specifically, for example, in 2014 there were 2,531 overdose deaths statewide. In 2015, there were 3,050 Ohio overdose deaths (a 20.5% increase from 2014).[114] In 2016, drug overdoses claimed the lives of 4,329 people across the State, a more than 30% increase in the number of lives lost over the previous year, according to data from the CDC. Reports from death certificates show that in 2016 alone, more than 86% of the fatalities involved opioids, including prescription opioids, heroin, and fentanyl.

371. In Ohio, 13 people die every day from drug overdoses on average. Provisional data from the CDC shows the death toll continuing to climb during the first half of last year, with 5,232 Ohio overdose deaths recorded in the 12 months ending June 31, 2017. Even these grim numbers, however, likely understate the number of lives lost, due to incomplete reporting.

372. Overdose deaths have become the leading cause of death for Ohioans under the age of 55, and across all ages, more than two and half times as many people die from drug overdoses as from car accidents. Most of the overdose fatalities in Ohio involved opioids (including prescription opioids, heroin, and illicitly manufactured synthetic opioids).

373. Eighty-five percent of these overdoses involved opioids.[115] The problem is only getting worse: between 2015 and 2016, overdose deaths in Ohio rose by nearly 33%.[116] And the overall number of drug overdose deaths attributable to all opioids rose from 85% in 2015 to 86.3 percent in 2016.[117]

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114 *See supra* n.14.

115 *Id.*

116 2016 Ohio Drug Overdose Data, *supra* n.14.

117 *Id.*

Table 1. Number of Unintentional Drug Overdose Deaths Involving Specific Drug(s), As Mentioned on Death Certificate, by Year, 2004-2016 [1-3]

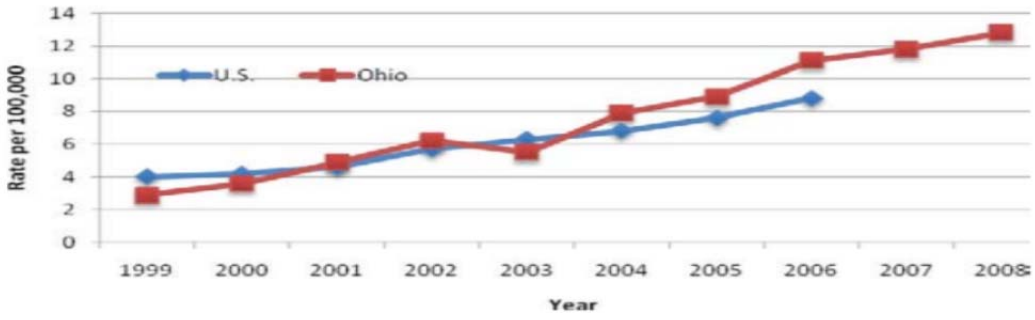
Drug Category	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	% of 2016 deaths
All opioids*	429	489	551	631	733	783	980	1,163	1,272	1,539	2,820	2,598	3,495	86.3%
Fentanyl & related drugs				75^	85^	72^	77^	73^	75	84	503	1,155	2,357	58.1%
Heroin	124	131	117	146	233	283	338	431	680	983	1,706	1,424	1,444	35.7%
Cocaine	223	223	317	287	252	220	213	309	326	405	517	685	1,109	27.4%
Prescription opioids**	319	388	462	435^	480^	482^	622^	724^	628	644	672	667	564	13.9%
Benzodiazepines	69	90	121	133	154	211	300	376	311	328	420	504	553	13.7%
Alcohol***	38	58	89	135	183	173	195	226	282	304	383	388	539	13.3%
Psychostimulants**** (e.g., Methamphetamines)	6	9	4	7	7	9	10	28	30	49	59	96	233	5.8%
Hallucinogens	8	8	10	13	14	9	26	31	31	43	48	61	100	2.5%
Methadone	116	144	161	176	168	168	155	156	123	112	103	108	94	2.3%
Barbiturates	3	5	3	7	3	5	13	11	6	10	6	19	14	0.3%
Other/unspecified drugs only*****	256	289	378	453	475	396	343	373	389	319	274	194	182	4.5%
Multiple Drug Involvement							808	908	1,016	1,014	1,321	1,747	2,451	60.5%
Total unintentional poisoning deaths	904	1,020	1,261	1,351	1,473	1,423	1,544	1,772	1,914	2,110	2,531	3,050	4,050	
Age-adjusted annual death rate per 100,000	7.9	8.9	11.0	11.8	12.9	12.7	13.7	15.4	17.0	18.7	22.7	27.7	36.8	

Source: Ohio Department of Health, Bureau of Vital Statistics; analysis conducted by ODH Violence and Injury Prevention Program.

374. The State of Ohio's death rate has grown faster than the national rate.[118] In fact, Ohio now "leads the country in drug overdose deaths per capita, a rate that continues to rise, overwhelming families, communities, and local governments across the state."

Ohio's death rate has grown faster than the national rate. In 1999, Ohio's unintentional drug overdose death rate was 2.9 per 100,000 compared to the national rate of 4.0 per 100,000 (Figure 1). In 2006, Ohio's unintentional drug poisoning death rate had risen to 11.1 per 100,000, compared to the national rate of 8.8 per 100,000. By 2008, Ohio's death rate rose to almost 13 per 100,000.[2]

Figure 1. Ohio[3] and U.S.[4] Unintentional Drug Overdose Death Rates per 100,000 Population, 1999-2006 (2008 for Ohio).

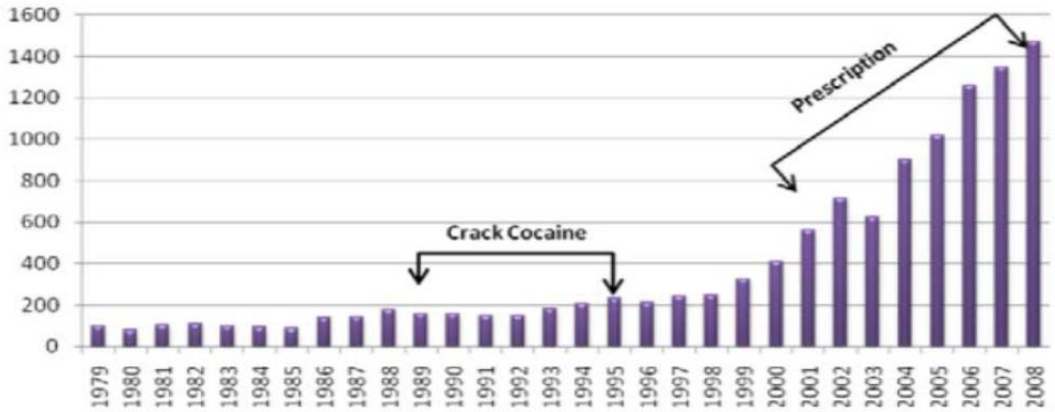


375. These figures make the opioid epidemic in Ohio one of the deadlier epidemics, measured by deaths and mortality rates. I n 2010, mortality rates were four to five times higher

118 *Id.*

than the rates during the "black tar" heroin epidemic in the mid-1970s, and more than three times what they were during the peak years of the crack cocaine epidemic in the early 1990s.[119]

Figure 4. Epidemics of unintentional drug overdoses in Ohio, 1979-2008.[12,13,14]

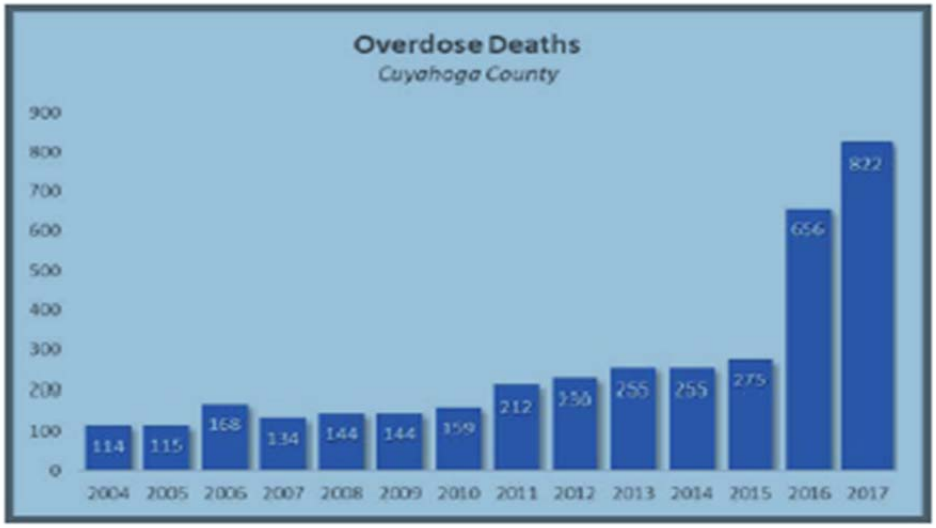


b. Cuyahoga County

376. Like the State of Ohio, Cuyahoga County saw similar increases in drug overdose deaths. In 2016, an average of 12 Cuyahoga County residents lost their lives to a drug overdose ***every week***. As the following chart indicates, the number of unintentional drug overdose totals in Cuyahoga County increased more than nearly 500% since 2004, from 114 lives lost in 2004 to 656 lives lost in 2016:[120]

[119] OHIO PRESCRIPTION DRUG ABUSE TASK FORCE, FINAL REPORT: TASK FORCE RECOMMENDATIONS (2010), *available at* https://www.odh.ohio.gov/health/vipp/drug/~/media/1F1DD52D1CA24ADBB98551AD588114EC.ashx (last accessed on June 25, 2018).

[120] *Supra* n.17.



377. There appears to be no end in sight for the number of overdose deaths for the population served by MetroHealth and its surrounding area. Based on preliminary numbers for 2017, at least 822 people died of overdoses in Cuyahoga County last year, surpassing the record set in 2016. The majority of these overdoses involved opioids, including both prescription opioids and nonprescription opioids such as heroin and fentanyl.

378. The number of opioid-related fatalities in Cuyahoga County now exceeds the total number of deaths from homicides, suicides, and car accidents combined. To quote the Cuyahoga County Medical Examiner, Dr. Thomas Gilson, Cuyahoga County is currently suffering a "slow moving mass fatality event that occurred last year, is occurring again this year and will occur again next year."[121]

379. So deadly is this trend that surges of fatal drug overdoses have outpaced the capacity of some local morgues. The Cuyahoga Medical Examiner has had to request the use of

[121] Andrew Cass, *Cuyahoga County medical examiner discusses opioid epidemic before U.S. Senate subcommittee*, NEWS-HERALD (May 25, 2017, 12:44 pm), http://www.news-herald.com/general-news/20170525/cuyahoga-county-medical-examiner-discusses-opioid-epidemic-before-us-senate-subcommittee.

a refrigerated trailer, known as a "mobile morgue unit" and originally intended for catastrophes, such as plane crashes leading to mass casualties, from the Ohio Department of Health.

4. Increased Hospitalizations and Related Health Care Costs

380. Unsurprisingly, the number of overdose and/or drug-related hospitalizations have increased as a result of the opioid epidemic.

381. As MetroHealth's community of physicians, nurses, and clinicians have worked to save lives, the opioid epidemic has continued to outpace their efforts. Opioid addiction is now the single largest reason that Ohioans seek substance use disorder treatment.

382. Injury and illness in Ohio extends well beyond even overdose hospitalizations. According to the CDC, an increase in Hepatitis C in the United States is directly tied to intravenous injection of opioids. Once again, Ohio is no exception to this trend. The number of cases of chronic Hepatitis C in Ohio nearly tripled from 2011 to 2015, an increase that resulted largely from intravenous use of drugs, including OxyContin and other prescription painkillers, stemming from the opioid epidemic. The co-morbidity is sufficiently high that the Ohio Department of Health recommends that women of childbearing age, who have tested positive for drugs and dependence, also receive screening for Hepatitis C and HIV.

383. In short, opioid addiction creates its own health issues for individuals, as well as exacerbating or making it more difficult to treat other non-opioid-related illnesses and injuries. The Marketing Defendants' deceptive conduct has resulted in MetroHealth being forced to shoulder the burden of these increased costs.

5. Neo-natal Care Costs

384. Even infants have not been immune to the impact of opioid addiction. There has been a dramatic rise in the number of infants who are born dependent on opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS"), also known as neonatal opioid

withdrawal syndrome or "NOWS"). These infants usually experience painful withdrawal from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS or NOWS can be life-threatening.

385. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

386. In Ohio, the number of infants born with NAS increased six-fold from 2004 to 2011. From 2009 to 2014, data from seven regional hospitals showed a greater-than six-fold increase in drug-exposed infants. As a whole, the State has seen an 816% increase in the number of infants born with NAS from 2006 to 2015, with opioids and other illegal narcotics being the most commonly implicated drugs since 2009. In 2015 alone, 2,174 infants were admitted to inpatient settings for this painful condition, an average of six per day. NAS has become so prevalent in Ohio communities that the Ohio Department of Health now recommends screening all newborns for this condition.

387. The increase of infants born with NAS is similarly being seen in the geographic area served by MetroHealth. For example, in 2010, 258 children in Cuyahoga County were born exposed to drugs, according to the County's Children's Services Division. By 2017, that number had doubled, jumping to 535. "It would be nice to say that we're near a plateau, but I don't think

so," said Scott Britton, the Deputy Director of the Public Children's Services Association of Ohio. "We just keep seeing the numbers going up and up."[122]

388. This dramatic rise in NAS may be described as an epidemic within an epidemic. According to the Ohio Perinatal Quality Collaborative, the "NAS epidemic is steadily increasing, overwhelming social service systems and public payers." In 2013, the average inpatient stay and bill for babies suffering from NAS was four times longer and higher than for other infants in Ohio. Newborns with NAS spent approximately 26,000 days in Ohio hospitals in 2014, with health care costs totaling $105 million.

389. In an effort to reduce the impact of the opioid crisis on infants, MetroHealth became part of the Maternal Opiate Medical Supports ("MOMS") program in 2010, which provides resources for pregnant women and mothers that struggle with opioid use during and after pregnancy. The goal of MOMS is to improve maternal and fetal health outcomes, improve family stability, and reduce costs associated with NAS.

390. That same year, MetroHealth also founded the Mother and Child Dependency Program. Since its creation in 2010, MetroHealth healthcare providers have cared for more than 1,000 pregnant women with opioid use disorder. As of 2017, 67% of the women in this program were well-enough established in their sobriety to take their babies home.

6. Direct Purchases of Opioids and Related Costs

391. Plaintiff has also been directly damaged through its payments for opioid therapy (and the frequent ensuing payments for addiction-related treatment) that was unwarranted and potentially dangerous for its employees, retirees, and their families by funding a medical

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[122] John Caniglia, *Cost of Opioid Epidemic Soars, Hitting Taxpayers Harder than Ever*, Cleveland.com (Oct. 8, 2017), http://www.cleveland.com/metro/index.ssf/2017/10/the_cost_of_the_opioid_epidemi.html.

insurance plan and workers' compensation program for its employees. MetroHealth effectively self-insures its employee health benefits.

392. That MetroHealth would incur the expense of paying for such ineligible prescriptions on behalf of its employees and their families was the foreseeable and intended consequence of Defendants' fraudulent marketing scheme.

393. MetroHealth has also shouldered significant health-related costs outside of its health insurance program as a result of Defendants' actions. For instance, when MetroHealth employees are prescribed opioids for chronic pain, they often are forced to miss work because the drugs' effects interfere with their ability to work.

394. In fact, recent studies suggest that opioids actually slow recovery times, keeping employees out of work longer than they would have been had they not taken these unnecessary pharmaceuticals. If those employees become addicted to opioids, they are likely to miss even more work. Because of Defendants' misstatements, MetroHealth's employees have had losses in work time, which result in substantial losses to MetroHealth.

395. And as set forth above, the direct costs of filling the opioid prescriptions is just a small part of the total cost to MetroHealth for prescriptions of opioids. MetroHealth effectively self-insures its workers' compensation plan, paying for doctor visits, lab work, and all costs related to opioid prescriptions. Had Defendants told the truth about the risks and benefits of opioids, MetroHealth would not have had to pay for these drugs or the costs related to their prescriptions.

396. As both the foreseeable and intended consequence of Defendants' fraudulent marketing scheme, health care providers prescribed and MetroHealth paid for opioids to treat chronic pain. Indeed, Defendants entire purpose of convincing the medical and general

community to support chronic opioid therapy was to get doctors to prescribe and payors, such as MetroHealth, to pay for long-term prescriptions of opioids to treat chronic pain, despite the absence of genuine evidence supporting chronic opioid therapy and the existence of evidence to the contrary.

397. MetroHealth relied, to its detriment, on Defendants' misrepresentations and thereby authorized and paid under its medical and health insurance plans and its workers compensation plans, for opioid medical treatments which are required under the plans to be medically necessary or reasonably required. But for Defendants' fraudulent and deceptive marketing, prescribers would have accurately understood the risks and benefits of opioids and would not have prescribed opioids when not medically necessary or reasonably required to treat chronic pain. Misrepresentations as to, for example, whether patients were likely to become addicted to the drug, would be able to resume life activities, and would experience long-term relief were not minor or insubstantial matters, but the core of prescribers' decision-making.

7. Expenses Related to Re-Education and Training

398. MetroHealth has been in the forefront of re-educating and re-training prescribers on safe and responsible opioid prescriptions. It began this initiative well before it was required to by the CDC or by the State of Ohio. Furthermore, the rigor of the re-training and enhanced protocols for the prescription of opioids far exceeds the standards set by the CDC or Ohio. To that end, MetroHealth has been forced to expend massive amounts of time, money, and resources on re-educating and re-training its providers on the appropriate way to prescribe opioid pain medications.

399. In 2017 MetroHealth opened the Office of Opioid Safety, which is comprised of 13 newly hired positions (11 fulltime and 2 part-time on an as-needed basis) exclusively devoted

to opioid safety, including a director, manager, several staff members, a "quick response" team staff member, and two medical educators.

400. The stated mission of the Office of Opioid Safety is to promote opioid safety throughout the MetroHealth System and community through education, advocacy and treatment. These measures comply with and are well in excess of Ohio and federal CDC guidelines.

401. For example, the Office of Opioid Safety provides educational resources and support for school nurses employed within the geographic area served by MetroHealth (including, but not limited to, nurses at the Cleveland and Lakewood School Districts) to identify drug use among students and to administer Narcan to students or their parents or guardians who have overdosed.

402. Beginning in January 2018, the Office of Opioid Safety also began conducting "town hall" style educational discussions twice a week with the goal of educating all 950 of MetroHealth's providers. Each such town hall discussion serves between 5-30 providers and educates MetroHealth's providers on safer opioid prescribing practices, the impact of state and federal laws pertaining to opioid prescribing, and how to integrate assessment and management tools to mitigate the risk of misuse and monitor adherence to regimen. To date, over 100 such town hall meetings have taken place. These meetings are led by Dr. Joan Papp, an assistant professor at the Case Western Reserve University School of Medicine who is Board Certified in Emergency Medicine. In addition to her work with MetroHealth, Dr. Papp chairs the U.S. Attorney for the Northern District of Ohio's policy subcommittee group on creating community action plan to combat the opioid addiction crisis, chairs the Opioid Response Initiative led by the Ohio Hospital Association and serves on the physician executive committee of the Opioid

Hospital Consortium, a northern Ohio collaborative whose aim is to address the opioid crisis within the hospital systems.

403. As an emergency physician at MetroHealth, Dr. Papp began seeing a large number of patients impacted by the opioid crisis: those who were addicted to prescription drugs; those who had transitioned to heroin; those suffering from complications of drug use; and increasing overdoses. In response, Dr. Papp launched Project DAWN (Deaths Avoided With Naloxone) in Cuyahoga County (as discussed below) in 2013 to provide the antidote to people on the front lines of the epidemic. According to Dr. Charles Emerman, Chairman of MetroHealth's Department of Emergency Medicine, Dr. Papp's efforts in founding Project DAWN were "remarkable, especially since they were undertaken in addition to her emergency room duties."[123] "She thought up the program, met with politicians and legal people and the Free Clinic . . . . She made the whole thing go."[124] "Her compassion, empathy and hard work have afforded her patients the ultimate opportunity: a second chance at life."[125] Far from hyperbole, Dr. Papp's efforts with Project DAWN have resulted in the reversal of approximately 1,650 opioid-related overdoses.[126]

404. As the opioid overdoses and related deaths continued to rise, Dr. Papp realized she and MetroHealth needed to do even more to address the deadly problem. She turned to MetroHealth leadership and lobbied to create the Office of Opioid Safety. According to Dr.

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123 Stan Bullard, *Advancements In Health Care, Safety Net: Dr. Joan Papp*, CRAIN'S CLEVELAND BUS. (May 4, 2014, 2:30 am), http://www.crainscleveland.com/article/20140504/HEROES14/305049976/advancements-in-health-care-safety-net-dr-joan-papp.

124 *Id.*

125 *Id.*

126 Lydia Coutré, *Dr. Joan Papp: Medical Director, Project DAWN, MetroHealth*, CRAIN'S CLEVELAND BUS. (Mar. 9, 2018, 11:54 am), *available at* http://www.crainscleveland.com/article/20180309/news/154416/dr-joan-papp.

Bernie Boulanger, Executive Vice President and Chief Clinical Officer at MetroHealth, "[w]ithout [Dr.] Papp, the Office of Opioid Safety wouldn't have been possible[.] . . . She's relentless, driven and passionate."[127] Put simply, she is "a warrior in the battle against opioids."[128]

405. Dr. Papp uses that warrior's spirit to passionately educate MetroHealth's prescribers on the real dangers of opioid pain medications. Each town-hall meeting runs approximately one hour and consists of a presentation by Dr. Papp, followed by a question and answer session with the 30 or so MetroHealth staff. The presentations gives prescribers a thorough understanding of the opioid crisis impacting Cuyahoga County, as well as a strong counterpoint to the Marketing Defendants' false messaging that opioids are the go-to for pain medication. Dr. Papp encourages questions and actively engages with prescribers in order to dispel misconceptions created by Defendants and to re-educate them as to the appropriate method of prescribing opioid pain medications.

406. MetroHealth spends substantial sums focusing on prevention, treatment, and recovery through a variety of educational programs for those suffering from an opioid use disorder. For instance, MetroHealth partially funds an opioid overdose education and naloxone distribution program, Project DAWN, that is designed for persons addicted to opioids and their friends and family.

407. Project DAWN participants are educated on the risk factors for opioid overdose, how to recognize an opioid overdose, and how to respond to an opioid overdose by calling 9-1-1, giving rescue breaths, and administering nasal naloxone. Eligible participants are given free naloxone kits, containing two doses of naloxone hydrochloride medication, at Project DAWN's

127 *Id.*

128 *Id.*

walk-in clinics. To date, nearly 10,000 naloxone kits have been distributed across the program's five walk-in clinics and community distribution events. Since 2013, MetroHealth has spent approximately $260,000 on Project DAWN. There have been nearly 10,0000 patient encounters in Project DAWN since 2013. This program is currently being expanded due to its urgent need.

408. MetroHealth has enacted additional protocols that exceed those requirements of the CDC and Ohio-mandated policies regarding opioid prescribing. For example, during MetroHealth's town hall meetings, Dr. Joan Papp instructs prescribers to (1) advise the patient that opioid pain medications can be addicting and to use the actual term "addicting" as an additional way to underscore the dangerousness of these drugs; and (2) advise the patient to discontinue storing unused opioid prescriptions in the medicine cabinet because those remaining prescriptions can be used by other people.

409. In 2017, MetroHealth formed the Opioid Executive Committee as a way to oversee an across-the-board reduction in number of opioid prescriptions issued by all MetroHealth prescribers. The Opioid Executive Committee is comprised of representatives of various departments within MetroHealth, including, but not limited to, MetroHealth's providers, quality representatives, police force and pharmacy, and it is chaired by MetroHealth's Chief Clinical Officer.

410. In order to achieve the goal of reducing the number of opioids prescribed while achieving patient pain relief, the Opioid Executive Committee formalized the Opioid Prescribing Initiative. This initiative, which had begun several years prior, has enabled MetroHealth to cut opioid prescriptions by 50% in just three and a half years; the number of opioids prescribed for acute pain by 62% in eighteen months; and the number of pills prescribed for chronic pain by 25%. All of this has resulted in approximately 3 million fewer pills prescribed per year.

411. Another step taken by the Opioid Executive Committee to reduce prescriptions of opioids generally was to update MetroHealth's prescription system (the "EPIC system"), which requires prescribers to document the details of the prescriptions they write for their patients. The EPIC system now includes warnings when a high dose is being prescribed and a best practice alert to encourage the co-prescribing of naloxone with all opioid prescriptions. MetroHealth also reduced the default quantities of opioid pills offered in the acute setting to 3, 5, or 7 day cycles of treatment. The process of updating the EPIC system took MetroHealth over 100 hours to complete and requires ongoing oversight to maintain.

412. At the direction of the Opioid Executive Committee, MetroHealth offers each of its prescribers a three-hour training program, where prescribers simulate methods to have effective and compassionate conversations with patients designed to reduce a patient's opioid pain medication intake while avoiding conflict over said reduction. Notably, this training is mandatory for selected MetroHealth providers who see a high population of patients on high doses of opioids. These training programs are administered by a medical educator that was hired as a full-time opioid educator.

413. MetroHealth has also launched a six-episode podcast series, "Prescription for Hope," which is dedicated to the opioid epidemic and how MetroHealth is battling it. The episodes highlight, among other things, Dr. Papp's work with Project DAWN and MetroHealth's Office of Opioid Safety and Dr. Paul Manning's work with the medication-assisted treatment programs (*See supra* ¶403; *infra* ¶431).

414. In addition to the mass re-education efforts MetroHealth has undertaken to reverse the damage caused by Defendants' deceptions, individual members of MetroHealth's staff have sought out additional certifications to better treat opioid-addicted patients.

415. In sum, MetroHealth allocates substantial portions of its budget to prevent, treat, and assist in recovery from opioid addiction and also spends substantial sums to prevent fatal opioid overdoses. But for Defendants' misconduct, MetroHealth would not have spent the massive amounts it has spent and will continue to spend in the future.

8. Unreimbursed Costs

416. As part of its mission to provide health care services to Cuyahoga County's indigent sick and disabled, inmate population, and children in foster care, MetroHealth has incurred unreimbursed and/or un-recouped costs of providing: (a) medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) counseling and rehabilitation services; (c) lost opportunity costs; (d) the diversion of assets from the provision of other needed health care; and (e) increased human resources costs, as well as lost productivity of its employees.

417. MetroHealth has also incurred unreimbursed and/or un-recouped costs with respect to providing security and public safety, as well as added regulatory compliance.

418. In total, in 2017 MetroHealth received $32 million from Cuyahoga County for indigent care expenses. MetroHealth provided an additional $160 million in free and subsidized care on top of that. In addition, MetroHealth provided another $71 million to support community programs, education, and research. Thus, MetroHealth provides approximately $231 million in community benefit. This is more than double the amount community support provided by the average U.S. hospital. .

9. Emergency Treatment Costs

419. The opioid crisis created by Defendants has also resulted in an increase in emergency room visits, emergency responses, and emergency medical technicians'

administration of naloxone, the antidote to opioid overdose. In fact, while the rate of opioid-related emergency department visits increased in almost all states from 2009 to 2014, Ohio experienced the greatest increase of any state in the nation, and the rate of opioid-related inpatient stays increased dramatically as well, according to data from the U.S. Agency of Healthcare Research and Quality. Similarly, MetroHealth experienced an increase in the rate of opioid-related hospitalizations.

420. MetroHealth also maintains its own EMS unit of first responders, who travel to and from emergency calls, transport patients to MetroHealth emergency rooms, and administer medical treatment to patients who are, among other things, overdosing on opioids.

421. Each drug-related overdose puts an enormous strain and burden on MetroHealth: (1) MetroHealth emergency room personnel, accompanied by MetroHealth police department and other social workers, intake overdose victims (frequently, these intakes are characterized as "code green" intakes, which refer to situations where the overdosing victim is literally dumped in front of the hospital door and the "friend" runs away out of fear of being implicated in the overdose and/or death of the overdosing victim); (2) MetroHealth provides the victim with medical treatment, including, but not limited to, administering naloxone as many times as necessary; and (3) indigent overdose victims are provided with transportation (paid for by MetroHealth) upon release. Providing this medical care and diverting these resources away from other care is costly, but necessary to combat the health crisis created by Defendants.

10. Law-Enforcement Costs

422. MetroHealth also maintains its own police department, consisting of 72 police officers.

423. As a result of the opioid epidemic created by Defendants, and the resulting increases in drug overdoses and hospitalizations, MetroHealth was required to spend and/or

allocate additional resources in order to increase the number of officers stationed in its emergency room.

424. In 2011, when the need for additional police officers began to arise, MetroHealth's emergency room only had one such officer. Today, there are never less than three officers on duty.

425. In 2018, MetroHealth trained all of its 72 police officers to administer naloxone. They now carry this life-saving remedy with them at all times. Within just three and a half months of implementing this change, MetroHealth police officers have saved eight lives.

11. Community Outreach Expenses

426. MetroHealth provides various programs to the community it serves, particularly with respect to drug addiction and treatment.

427. In April 2018, as part of its ongoing efforts to respond to the opioid epidemic in Cuyahoga County, the Office of Opioid Safety launched two opioid Quick Response Teams as part of its Hope After Overdose Outreach Project ("HOOP").

428. The Quick Response Teams partner with the Westshore Enforcement Bureau ("WEB") and the City of Parma Police Department. The teams are made up of a MetroHealth social worker and a police officer from the partnering departments. Each Quick Response Team attempts to contact overdose victims and their families at their homes within seven days of a documented overdose and provide information and/or education on treatment and overdose response. The Quick Response Teams provide each victim with a free naloxone kit during such visits.

429. MetroHealth's HOOP and the Quick Response Teams are funded by a multi-year $1.9 million grant from the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration ("SAMHSA"). This grant, however, is not

guaranteed and MetroHealth would shoulder all the costs of such outreach programs should the grant be rescinded.

430. Additionally, MetroHealth also provides outpatient medication-assisted treatment ("MAT") for opioid dependence, which consists of counseling and other behavioral oriented support measures. However, access to MAT remains inadequate at MetroHealth. National health experts universally agree that MAT, including buprenorphine or Suboxone – the first drug approved to treat opioid addiction that can be prescribed or dispensed in physician offices – is vital to recovery. But in 2016, only 273 physicians in Ohio were certified to treat 30 patients at a time, and only 104 physicians were certified to treat 100 patients at a time.

431. Based on the limited numbers of buprenorphine-licensed physicians statewide, only 18,000 opioid-dependent patients could have received buprenorphine treatment from a private physician in 2016 – not nearly enough, given a 2017 study's estimate that 92,000 to 170,000 Ohioans are either abusing or dependent upon opioids.[129] Buprenorphine treatment is similarly scarce in MetroHealth. In fact, in the face of the rapidly increasing number of patients addicted to opioids, MetroHealth realized that it simply did not have enough prescribers who were certified to prescribe the various approved medications for opioid addiction, such as vivitrol buprenorphine (a.k.a. Suboxone). In response, Dr. Paul Manning personally took a year off to become certified as an addiction specialist authorized to prescribe Suboxone (one of three approved medications for opioid addiction) for MetroHealth. After becoming a certified prescriber of medication-assisted treatment, Dr. Manning established a walk-in outpatient clinic in the City of Parma that provides Suboxone to recovering addicts. On the first day this

[129] Mark Rembert, et al., *Taking Measure of Ohio's Opiate Crisis*, OSU Swank Program in Rural-Urban Policy (October 2017), *available at* https://cpb-us-w2.wpmucdn.com/u.osu.edu/dist/2/14548/files/2017/10/SWANK-TakingMeasure-of-Ohios-Opioid-Crisis-1vtx548.pdf.

Suboxone clinic was announced, MetroHealth received over 200 calls inquiring about access. Recently, MetroHealth's Chairman of Emergency Medicine, Dr. Charles Emerman, also sought out additional training in addiction treatment and became board certified in addiction medicine.

432. Additional funds are needed to expand access to MAT.

433. MetroHealth has also created a protocol for distributing naloxone in the surrounding geographical area.

434. Dr. Papp, as a part of the community outreach mission of Project DAWN, heads a team that staffs Project DAWN walk-in clinics at three partnering organizations including, Circle Health Services, Hispanic UMADAOP, and the Cuyahoga County Board of Health. Two other partnering organizations, Cleveland Emergency Medical Services (EMS) and Cleveland Department of Public Health's McCafferty Health Center help to supply MetroHealth lead Project DAWN walk-in clinics with existing agency staff. MetroHealth Project DAWN walk-in clinics staff provide free naloxone kits and educate people on opioid addiction, recognizing an overdose, and what to do if one occurs. MetroHealth Project DAWN staff also conduct weekly education and distribution sessions in Cuyahoga County connecting with agencies and people at risk of opioid overdose or their family members, friends or others who may come into contact individuals at risk of overdose. In addition, Dr. Papp and her team also work alongside Circle Health Service's syringe van, which exchanges used syringes for new ones to help avoid HIV and other diseases.

435. The strain on MetroHealth's budget will continue for the foreseeable future and is likely to increase. Addiction is currently considered to be a brain illness that may be brought into remission, but there is no known cure for that devastating disease. It is also known to be a

disease where relapses are common.[130] Accordingly, even if the epidemic were stopped in its tracks right now, the damages to MetroHealth would continue until the health crisis is abated, which will likely take years, if not decades.

12. Funding From Grants Are Not Enough

436. Cuyahoga County provides MetroHealth with a grant of approximately $34 million annually, which constitutes about 3% of MetroHealth's operating budget, so that MetroHealth can provide healthcare to the County's uninsured and indigent populations. In reality, however, the cost of providing such care is actually much higher. MetroHealth devotes approximately 10% of its operating budget to serving the County's indigent population.

437. Put simply, MetroHealth is already operating at a loss when it comes to providing healthcare to Cuyahoga County's most vulnerable population. As discussed more thoroughly above, a significant amount of resources have been, and continue to be, devoted towards drug addiction and treatment.

438. But even with this substantial commitment, MetroHealth is well short of what it needs to treat the growing number of individuals with opioid-use disorder in Cuyahoga County. The cost of providing treatment beds in the County alone jumped from $4.9 million in 2014 to $9.9 million in 2017, an increase of 102% in just three years. And while MetroHealth provides beds in a variety of treatment programs, more are needed to avoid the premature release of recovering individuals, who, in many instances, return to their homes only to relapse.

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[130] Thomas R. Kosten, M.D. & Tony P. George, M.D., *The Neurobiology of Opioid Dependence: Implications for Treatment*, 1 SCI. & PRACT. PERSP. 13 (2002), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2851054/.

439. Virtually every department within MetroHealth has been impacted and forced to incur additional expenses year after year to try to mitigate the devastating impact of the opioid epidemic to MetroHealth's residents.

440. In short, by virtue of the deceptive and fraudulent marketing campaign of the Defendants, MetroHealth has incurred expenditures in the tens of millions of dollars and will continue to incur those, in addition to even greater expenditures in the foreseeable future, as the man-made epidemic continues to unfold.

V. CAUSES OF ACTION

COUNT I
Public Nuisance
(Against All Defendants)

441. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

442. MetroHealth is the county hospital responsible for providing medical health care to Cuyahoga County's indigent sick and disabled population. In addition, it is a nationally ranked, public health care system that cares for the health of all citizens of Cuyahoga County, providing education for public school nurses, caring for the health of all prisoners in the County, and providing health care to all foster care children in the County. As the overseer and protector of public health, MetroHealth is the proper plaintiff to bring this action.

443. MetroHealth, and the community it serves, has a common right to be free from conduct that constitutes an unreasonable interference with the public health and safety. Defendants, through their conduct described in this Complaint, have created a public nuisance that constitutes a significant, unreasonable interference with this common right. Further, this interference is continuing in nature and has produced a long-lasting effect, and Defendants knew or had reason to know the devastating effects their conduct would have upon MetroHealth.

444. Defendants have intentionally, recklessly, and negligently marketed their opioid products through materially false and misleading statements to physicians, pharmacists, insurers, and members of the general public that misrepresented the characteristics and safety of opioids and resulted in widespread, inappropriate use of these highly addictive and dangerous pharmaceuticals. Through their promotion, marketing, and distribution of prescription opioids for profit, all Defendants created an epidemic of addiction and overdoses on prescription and non-prescription opioids, such as heroin and fentanyl, that constitutes a public nuisance in the geographic area served by MetroHealth.

445. As such, Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety, and welfare of the patient population of MetroHealth, and the ability of MetroHealth to carry out its mission. MetroHealth has a clearly ascertainable right to abate conduct that perpetuates this nuisance.

446. Defendants' conduct has substantially and severely injured the public health, safety, and welfare of the geographic area surrounding MetroHealth and its patient population on many levels. These injuries include, without limitation: causing death and serious injury; rendering many of MetroHealth's patients incapable of participating in the labor force, caring for their families, participating in civic life, or leading independent lives; impairing Cuyahoga County residents' enjoyment of public spaces free from interference and harassment; and blight occasioned by the greatly increased population of addicted individuals created by Defendants' conduct.

447. The public nuisance created by Defendants' conduct has directly and proximately caused monetary harm to MetroHealth. The special injuries suffered by MetroHealth as a result of the public nuisance created by Defendants are distinct from those suffered by the general

public, and they include, but are not limited to, MetroHealth's payments for unsafe and unnecessary opioids pursuant to its payor programs, such as employee health insurance and workers' compensation, unrecouped or unreimbursed costs and expenses MetroHealth has incurred in the provision of medical treatment to Cuyahoga County's indigent sick, and disabled, its expenditures for many preventive, re-education, and rehabilitation efforts, as well as diversions from its other programs necessitated by the devastating increase in opioid addictions.

448. The public nuisance is an *absolute* public nuisance because Defendants' nuisance-creating conduct was intentional, unreasonable, and/or violated statutes which established specific legal requirements for the protection of others.

449. Under Ohio common law MetroHealth has a clearly ascertainable right to require Defendants to cease all conduct that perpetuates the nuisance, and to fund all abatement costs necessary to clean up the nuisance.

COUNT II
Violations of Racketeer Influenced and Corrupt Organizations Act,
18 U.S.C. §1961, *et seq.*
(Against the Marketing Defendants)

450. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

451. This Claim is brought by MetroHealth against the Marketing Defendants for actual damages, treble damages, equitable relief, and attorney' fees under the federal Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1961 *et seq*.

452. The Marketing Defendants are all enterprises within the meaning of 18 U.S.C. § 1961(4).

453. As described above, the Marketing Defendants fraudulently promoted and/or distributed opioids in Cuyahoga County, which is the area served by MetroHealth.

The Fraudulent Marketing Enterprise

454. All the Marketing Defendants, through the use of Front Groups that appeared to operate independently of the Markeing Defendants; through the dissemination of publications that supported the Marketing Defendants' scheme; through CME programs controlled and/or funded by the Marketing Defendants; by the hiring and deployment of so-called "Key Opinion Leaders" who were paid by the Marketing Defendants to promote their message; and through the "detailing" activities of the Marketing Defendants' sales forces, form an association-in-fact enterprise (the "Fraudulent Marketing Enterprise") for the common and continuing purpose described herein (*i.e.*, to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain), and constitute an enterprise within the meaning of 18 U.S.C. § 1961(4).

455. The Fraudulent Marketing Enterprise is an ongoing organization that engages in, and whose activities affect, trade and commerce.

456. While each of the Marketing Defendants has participated in and is a member of the Fraudulent Marketing Enterprise, each also exists separately and distinctly from the enterprise.

457. As set forth above, each Fraudulent Marketing Enterprise has an ascertainable structure separate and apart from the pattern of racketeering activity in which the Marketing Defendants have engaged.

Operation and Control

458. The Fraudulent Marketing Enterprise alleged above is an association-in-fact enterprise that consists of the Marketing Defendants (Purdue, Cephalon, Teva, Janssen, Endo, and Mallinckrodt); the Front Groups (APF, AAPM, APS, FSMB, USPF, AGS, and the Pain Care

Forum); the KOLs (non-defendants Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman), and Individual Defendants.

459. The Marketing Defendants have controlled and operated the Fraudulent Marketing Enterprise by, among other things: (a) funding the Front Groups and KOLs for the purpose of promoting the sale of their opioid products; (b) providing research and data regarding the purported uses and safety of their opioid products to the Front Groups and KOLs for use in educational and CME materials, and physician handbooks/brochures; and (c) financing and/or sponsoring CMEs which are used to promote the purported uses and safety of opioids for long-term use.

460. Each of the Marketing Defendants and the other members of the Fraudulent Marketing Enterprise conducted and participated in the conduct of the Fraudulent Marketing Enterprise by playing a distinct role in furthering the enterprise's common purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use and the risks and symptoms of addiction; this was done to change prescriber habits and public perceptions and thereby increase the market for opioids.

461. Specifically, the Marketing Defendants each worked together to coordinate the enterprise's goals and conceal their roles and the enterprise's existence from the public by, among other things, (i) funding, editing, and distributing publications that supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly to physicians (a

practice known as sales detailing) and, in particular, to physicians lacking the expertise of pain care specialists.

462. Each of the Front Groups helped disguise the role of Marketing Defendants by purporting to be unbiased, independent patient-advocacy and professional organizations, in order to disseminate patient education materials, a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted the Marketing Defendants' false messages.

463. The KOLs were physicians chosen and paid by each of the Marketing Defendants to influence their peers' medical practice by promoting the Marketing Defendants' false messages through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring the Marketing Defendants' role in the enterprise and the enterprise's existence.

464. Furthermore, each of the Marketing Defendants, KOLs, and Front Groups that made up the Fraudulent Marketing Enterprise had systematic links and personal relationships that were formed and developed to allow members of the Fraudulent Marketing Enterprise to form the common purpose and agreement to conduct and participate in the conduct of the Fraudulent Marketing Enterprise. Specifically, each of the Marketing Defendants coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry-friendly and would work with Marketing Defendants to advance the common purpose of the Fraudulent Marketing Enterprise; each of the individuals and entities that formed the Fraudulent Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Fraudulent Marketing Enterprise.

Predicate Acts

465. The Marketing Defendants have controlled and operated the Fraudulent Distribution Enterprises by, among other things, engaging in "racketeering activity," which is

defined under 18 U.S.C. § 1961(1) as any act indictable under 18 U.S.C. §1341 (relating to mail fraud) and 18 U.S.C. §1343 (relating to wire fraud). As set forth below, Defendants engaged in conduct violating each of these laws to effectuate their scheme.

466. For the purpose of executing and/or attempting to execute the above-described scheme to defraud or obtain money by means of false or fraudulent pretenses, representations or promises, the Marketing Defendants, in violation of 18 U.S.C. §1341, caused matter and things to be delivered by the Postal Service or by private or commercial interstate carrier, and/or received matter and things from the Postal Service or private or commercial interstate carriers. These acts were done intentionally and knowingly with the specific intent to advance Defendants' scheme, or with knowledge that the use of the mails would follow in the ordinary course of business, or that such use could have been foreseen, even if not actually intended.

467. For the purpose of executing and/or attempting to execute the above-described scheme to defraud or obtain money by means of false pretenses, representations or promises, the Marketing Defendants, in violation of 18 U.S.C. §1343, transmitted, caused to be transmitted and/or received by means of wire communication in interstate and foreign commerce, various writings, signs, and signals. These acts were done intentionally and knowingly with the specific intent to advance the Marketing Defendants' scheme, or with knowledge that the use of wire communications would follow in the ordinary course of business, or that such use could have been foreseen, even if not actually intended.

468. The matter and things sent by the Marketing Defendants via the Postal Service, private or commercial carrier, wire or other interstate electronic media include, *inter alia*, marketing materials such as press releases, educational and CME materials, and/or physician handbooks or brochures, which the Marketing Defendants and the other participants in the

Fraudulent Marketing and Enterprise utilized to fraudulently promote and distribute opioid products.

469. Other matter and things sent through or received from the Postal Service, private or commercial carrier or interstate wire transmission by the Marketing Defendants included information or communications in furtherance of or necessary to effectuate the scheme.

470. The Marketing Defendants' misrepresentations, acts of concealment and failures to disclose were knowing and intentional, and were made for the purpose of deceiving Plaintiff and obtaining its property for Defendants' gain.

471. The Marketing Defendants either knew or recklessly disregarded the fact that the misrepresentations and omissions described above were material, and Plaintiff relied on the misrepresentations and omissions as set forth above.

472. As a result, the Marketing Defendants have obtained money and property belonging to Plaintiff, and Plaintiff has been injured in its business or property by the Defendants' overt acts of mail and wire fraud.

Pattern of Racketeering Activity

473. The Marketing Defendants each committed or aided and abetted in the commission of at least two acts of racketeering activity, *i.e.*, indictable violations of 18 U.S.C. §§1341 and 1343, and the Federal False Claims Act, 31 U.S.C. §3729, as described above, within the past ten years. In fact, the Marketing Defendants collectively have committed thousands of acts of racketeering activity. The acts of racketeering activity were not isolated, but rather had the same or similar purpose, participants, method of commission, and victims, including Plaintiff.

474. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint, and, upon information and belief, will continue unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

475. The multiple acts of racketeering that the Marketing Defendants committed and/or conspired to commit, or aided and abetted in the commission of, were continuous. There was repeated conduct in a closed, but substantial, period of time. This conduct therefore constituted a "pattern of racketeering activity" as defined in 18 U.S.C. § 1961(5).

Injury Caused and Relief Sought

476. The Marketing Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property. The Marketing Defendants' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. Plaintiff's injuries, as described below, were not unexpected, unforeseen, or independent. Rather, as Plaintiff alleges, the Marketing Defendants knew that the opioids were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the Marketing Defendants engaged in a scheme of deception that utilized the mail and wires in order to carry out the Fraudulent Marketing Enterprise's fraudulent scheme, thereby increasing sales of their opioid products.

477. It was foreseeable and expected that the Marketing Defendants' creation of and participation in the Fraudulent Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.

478. Specifically, the Marketing Defendants' creation of, and then participation in, the Fraudulent Marketing Enterprise through a pattern of racketeering activities to carry out their fraudulent scheme has injured Plaintiff in the form of substantial losses of money and property that logically, directly, and foreseeably arise from the opioid-addiction epidemic. Plaintiff's injuries, as alleged throughout this Complaint, and expressly incorporated herein by reference, include:

(a) Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

(b) Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

(c) Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from anoxic brain injury caused by an overdose;

(d) Costs for providing healthcare and medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from injection-related disease including hepatitis C, heart valve infections and skin infections;

(e) Costs of training physicians, nurse practitioners, physician assistants, and other hospital personnel in the proper methods for prescribing opioid pain medication and for treatment of opioid overdoses and addiction;

(f) Costs associated with providing the community served by MetroHealth with naloxone, an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

(g) Costs for providing mental-health services, treatment, rehabilitation services, and social services to victims of the opioid epidemic and their families;

(h) Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mothers during pregnancy; and

(i) Unrecouped or unreimbursed costs of providing medical treatment to Cuyahoga County's indigent sick and disabled.

479. Plaintiff's injuries were directly and proximately caused by these Marketing Defendants' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiff's injuries. But for the opioid addiction epidemic the Marketing Defendants created through their Fraudulent Marketing Enterprise, Plaintiff would not have lost money or property.

480. Plaintiff is the most directly harmed entity and there is no other plaintiff better suited to seek a remedy for the economic harms at issue here.

481. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*:

(a) Actual damages and treble damages, including pre-suit and post-judgment interest;

(b) An order enjoining any further violations of RICO;

(c) An order enjoining any further violations of any statutes alleged to have been violated in this Complaint;

(d) An order enjoining the commission of any tortious conduct, as alleged in this Complaint;

(e) An order enjoining any future marketing or misrepresentations regarding the health benefits or risks of prescription opioids use;

(f) An order enjoining any future marketing of opioids through non-branded marketing, including through the Front Groups, KOLs, websites, or in any other manner alleged in this Complaint that deviates from the manner or method in which such marketing has been approved by the FDA;

(g) An order enjoining any future marketing to vulnerable populations, including but not limited to persons over the age of 55, anyone under the age of 21, and veterans;

(h) An order compelling the Marketing Defendants to make corrective advertising statements that shall be made in the form, manner and duration determined by the Court, but not less than print advertisements in national and regional newspapers and medical journals, televised broadcast on major television networks, and displayed on their websites, concerning: (1) the risk of addiction among patients taking opioids for pain; (2) the ability to manage the risk of addiction; (3) the depiction of pseudoaddiction as real addiction, not a sign of undertreated addiction; (4) the difficult nature of managing withdrawal from opioids; (5) the significant risks, including addiction and overdose, associated with increasing opioid dosage; (6) the lack of any demonstrated improvement of function with the long-term use of opioids; (8) the ineffectiveness of time-released

opioids in preventing addiction; and (9) the ineffectiveness of abuse-deterrent formulations in preventing opioid addiction;

(i) An order enjoining any future lobbying or legislative efforts regarding the manufacture, marketing, distribution, diversion, prescription, or use of opioids;

(j) An order requiring all Defendants to publicly disclose all documents, communications, records, data, information, research, or studies concerning the health risks or benefits of opioid use, including identification of all funders for such research or studies;

(k) An order prohibiting all Defendants from entering into any new payment or sponsorship agreement with, or related to, any: Front Group, trade association, doctor, speaker, CME, or any other person, entity, or association, regarding the manufacture, marketing, distribution, diversion, prescription, or use of opioids;

(l) An order establishing a national foundation for education, research, publication, scholarship, and dissemination of information regarding the health risks of opioid use, and evidence-based treatments for opioid addiction; all to be financed by the Defendants in an amount to be determined by the Court;

(m) An order divesting each Defendant of any interest in, and the proceeds of any interest in, the Fraudulent Marketing Enterprise, including any interest in property associated with the Fraudulent Marketing Enterprise;

(n) Suspension and/or revocation of the license, registration, permit, or prior approval granted to any Defendant, entity, association or enterprise named in the Complaint regarding the manufacture of opioids;

(o) Forfeiture as deemed appropriate by the Court; and

(p) Attorneys' fees and all costs and expenses of suit.

COUNT III
Violations of the Ohio Corrupt Practices Act,
Ohio Revised Code § 2923.31, *et seq*.
(Against the Marketing Defendants)

482. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

483. Plaintiff brings this Claim against Defendants Purdue, Cephalon, Janssen, Endo, and Mallinckrodt (referred to collectively for this Claim as the "the Marketing Defendants"), each of whom is a "person" within the meaning of Ohio Revised Code Section 2923.31(G).

The Fraudulent Marketing Enterprise and Pattern of Corrupt Activity

484. As alleged above, each of the Marketing Defendants were members of an association-in-fact enterprise, the Fraudulent Marketing Enterprise, within the meaning of Ohio Rev. Code Ann. § 2923.31(C).

485. As alleged above, each of the Marketing Defendants conducted and participated in the conduct of the affairs of the Fraudulent Marketing Enterprise through a pattern of "corrupt activities," as defined in Ohio Rev. Code Ann. § 2923.31(1) and (2).

486. As previously alleged, the Marketing Defendants engaged in a pattern of corrupt activity by committing mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343).

487. The Marketing Defendants' acts also constitute a pattern of telecommunications fraud (Ohio Rev. Code Ann. § 2913.05). The Marketing Defendants formed an association-in fact enterprise consisting of "advocacy groups and professional societies" ("Front Groups") and paid "physicians affiliated with these groups" ("KOLs") in order to unlawfully increase the demand for opioids. Through their personal relationships, the Marketing Defendants and members of the Fraudulent Marketing Enterprise had the opportunity to form and take actions in

furtherance of the Fraudulent Marketing Enterprise's common purpose. The Marketing Defendants' substantial financial contribution to the Fraudulent Marketing Enterprise, and the advancement of opioid-friendly messaging, fueled the U.S. opioids epidemic.

488. The Marketing Defendants, through the Fraudulent Marketing Enterprise, made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use, including: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Marketing Defendants called "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

Injury Caused and Relief Sought

489. The Marketing Defendants' violations of law and their pattern of racketeering activity directly or indirectly caused Plaintiff's injury. The Marketing Defendants' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. Plaintiff's injuries, as described below, were not unexpected, unforeseen or independent. Rather, as Plaintiff alleges, the Marketing Defendants knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, and for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the Marketing Defendants engaged in a scheme of deception that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products.

490. It was foreseeable and expected that a massive marketing campaign utilized by the Marketing Defendants that misrepresented the non-addictive and effective use of prescription opioids for purposes for which they are not suited and not approved by the FDA would lead to a nationwide opioid epidemic. It was also foreseeable and expected that the Marketing Defendants' marketing campaign would lead to increased opioid addiction and overdose. Plaintiff's injuries were logically, foreseeably, and substantially caused by the opioid epidemic that the Marketing Defendants created.

491. Specifically, the Marketing Defendants' predicate acts and pattern of racketeering activity caused the opioid epidemic, which has injured Plaintiff in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic. Plaintiff's injuries, as alleged throughout this Complaint, and expressly incorporated herein by reference, include:

(a) Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

(b) Costs for providing healthcare and medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

(c) Costs of training physicians, nurse practitioners, physician assistants, and other hospital personnel in the proper methods for prescribing opioid pain medication and for treatment of opioid overdoses and addiction;

(d) Costs associated with providing the community serviced by MetroHealth with naloxone, an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

(e) Costs for providing mental-health services, treatment, rehabilitation services, and social services to victims of the opioid epidemic and their families;

(f) Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mothers during pregnancy; and

(g) Unrecouped or unreimbursed costs of providing medical treatment to Cuyahoga County's indigent sick and disabled residents.

492. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*: actual damages; treble damages; equitable and/or injunctive relief, including corrective statements, information and education, under Ohio Rev. Code § 2923.34(B)(1)-(2), requiring divestiture by, and reasonable restrictions upon, the future activities of the Defendants; forfeiture as deemed proper by the Court; all costs and attorney's fees; expenses of suit; pre- and post-judgment interest; and all of the relief sought in the First Claim for Relief, as the Court deems just and applicable.

COUNT IV
Civil Conspiracy
(Against all Defendants)

493. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

494. As set forth herein, Defendants engaged in a concerted action civil conspiracy to create a public nuisance in conjunction with their unlawful marketing, sale, distribution and/or diversion of opioids into the State and Plaintiff's community, all in furtherance of Defendants'

effort to expand the market for opioids for their own gain, regardless of the devastating consequences to Plaintiff.

495. As set forth herein, each Defendant engaged in a civil conspiracy with the other Defendants to engage in the torts of negligent misrepresentation, negligence and fraud in conjunction with their unlawful distribution and diversion of opioids into the State and Plaintiff's community.

496. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

497. Defendants unlawfully marketed and promoted opioids in the State of Ohio and Plaintiff's community in furtherance of that conspiracy.

498. Defendants deliberately took affirmative steps in agreement and/or in concert with each other and/or in pursuit of a common design, and Defendants knew each other's conduct constituted a tortious breach of their legal duties owed to Plaintiff. Further, each Defendant provided substantial assistance and/or encouragement to the other Defendants with knowledge and in furtherance of their tortious plan.

499. Defendants' conspiracy is a continuing conspiracy.

500. Defendants acted with agreement and a common understanding or design to commit unlawful acts and/or lawful acts unlawfully, as alleged herein, and acted purposely, without a reasonable or lawful excuse, to create the injuries alleged herein.

501. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, proximately caused and/or substantially contributed to the direct and foreseeable losses alleged herein.

COUNT V
Negligence
(Against All Defendants)

502. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

503. All Defendants have a duty to exercise reasonable care in the distribution of opioids.

504. Violations of statutes and regulations are evidence of negligence where the harm sustained by Defendants' statutory or regulatory violations is the type sought to be prevented and the violations proximately caused the Plaintiff's injuries.

505. All Defendants' negligent conduct involved violations of Ohio statutory law, and the harm caused by the negligence was the type sought to be prevented by the statute.

506. Ohio Revised Code §1345.02 states that it is unlawful to make representations concerning "performance characteristics . . . uses, or benefits" of a product or service "that it does not have," including representations concerning drugs. It is also unconscionable under Ohio law to "knowingly take[ ] advantage of the inability of the consumer reasonably to protect the consumer's interest because of the consumer's . . . ignorance" or make misleading statements "on which the consumer was likely to rely to the consumer's detriment." R.C. § 1345.03(B)(1) & (6). False advertising constitutes any advertisement that is "false or misleading in any particular." R.C. 3715.68(A).

507. By disseminating false advertisements of their opioid drugs (and authorizing and sanctioning such conduct), Defendants violated Ohio Revised Code §§ 1345.02(B)(1), 1345.03(B)(1) & (6), which constitutes negligence under Ohio law.

508. Ohio Revised Code § 2913.47(B) makes it a crime for any person to knowingly submit claims under an insurance policy with the "purpose to defraud" or to facilitate the defrauding of any insurer.

509. The Marketing Defendants, with the knowledge and approval of the Individual Defendants committed insurance fraud throughout the geographical area served by MetroHealth through its unlawful selling and marketing of powerful opioids to insurance companies. Through this unlawful scheme, the Marketing Defendants misrepresented to insurance providers that, among other things, their respective prescription opioids were safe when used for chronic, non-cancer pain, when the Marketing Defendants and Individual Defendants knew that these drugs were highly addictive and unsafe for prolonged use.

510. Defendants' violations of the statutory standards set forth in Ohio state law, including, but not limited to, Ohio Revised Code § 2913.47(B), constitute negligence under Ohio law.

511. Defendant' violations of various civil and criminal laws were and are a substantial factor in the injuries and damages sustained by Plaintiff.

512. As a direct and proximate result of the lack of reasonable care exercised by Defendants in conducting their business of distributing pharmaceutical products at the wholesale level, the geographical area served by MetroHealth was flooded with opioids and opioid prescriptions well beyond any legitimate medical need.

513. As a direct and foreseeable consequence of Defendants' negligent conduct, Plaintiff has been damaged as alleged herein. Defendants' violations of state and federal statutes, and public safety regulations cited herein, were and are substantial factors in the injuries and damages sustained by Plaintiff.

514. It was foreseeable that Defendants' breach of statutory and regulatory laws described herein would result in the damages sustained by Plaintiff.

515. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' negligence.

COUNT VI
Negligent Misrepresentation
(Against All Defendants)

516. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

517. Defendants have failed to exercise reasonable care in the marketing of their opioid products.

518. All Marketing Defendants, individually and through third parties, represented that prescription opioids are relatively safe for the management of chronic pain, or made material misrepresentations about the safety of long-term opioid use for chronic pain, when they knew, or should have known, that opioids are highly addictive and have a high risk of overdose, death, or life-long damage to the brain of the person who is administered the drug for a medical indication for which it is not appropriate or for a time period or dosage that is inappropriate.

519. All Marketing Defendants, with the approval and encouragement of the Individual Defendants, made these material misrepresentations and omissions with the intent that MetroHealth and the residents of the geographic area surrounding MetroHealth would rely on them, and it was reasonably foreseeable to Defendants that such reliance would result in the use of opioid prescriptions by persons in quantities and for durations that would cause death or severe harm.

520. MetroHealth and its patient population did, in fact, rely on the Marketing Defendants' false, misleading and unconscionable statements, and MetroHealth has sustained

ascertainable losses as a direct and proximate result. Further, Defendants intended to deceive the physicians who prescribed opioids to the patient population and in the geographical area served by MetroHealth and the payors who purchased, or covered the purchase of, opioids for chronic pain.

521. In justifiable reliance on these incorrect statements, which reliance was foreseeable to Defendants, physicians prescribed opioids for chronic pain, insurers and third-party payors (including Plaintiff) paid for them, and patients took them to devastating effect as described herein. Additionally, MetroHealth incurred expenditures, including but not limited to:

(a) Costs of prescription drugs, including opioids;

(b) Costs of MetroHealth payor programs;

(c) Health services for the treatment of addiction and overdoses;

(d) Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

(e) Costs for providing healthcare and medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

(f) Costs of training physicians, nurse practitioners, physician assistants, and other hospital personnel in the proper methods for prescribing opioid pain medication and for treatment of opioid overdoses and addiction;

(g) Costs associated with providing the community serviced by MetroHealth with naloxone, an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

(h) Costs for providing mental-health services, treatment, rehabilitation services, and social services to victims of the opioid epidemic and their families;

(i) Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy; and

(j) Unrecouped or unreimbursed costs of providing medical treatment to Cuyahoga County's indigent sick and disabled, which MetroHealth would not have incurred but for the unfair and deceptive acts and practices of Marketing Defendants.

522. Plaintiff has thus been damaged as alleged herein, as a direct and foreseeable consequence of Defendants' negligent misrepresentations.

COUNT VII
Common Law Fraud
(Against All Defendants)

523. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

524. Marketing Defendants and Individual Defendants, individually and acting through third parties, made to the patient population of MetroHealth untrue, false, misleading, and deceptive statements and omissions of material facts regarding the nature, risks, and benefits of opioids and their use, which statements and omissions Defendants knew were untrue, false, misleading, and deceptive.

525. By making these untrue, false, misleading, and deceptive statements and omissions, Defendants intended that the patient population of MetroHealth would rely on them, and that such reliance would result in the purchase and use of opioid prescriptions in the manner promoted and marketed by such Defendants and for Defendants' gain.

526. Defendants' false representations of fact and material omissions of fact had their intended effect in that they caused the patient population of MetroHealth to view opioids as a safe and effective treatment for long-term chronic pain, leading to a huge and dangerous increase in opioid usage in the geographical area served by Plaintiff.

527. Because the patient population of MetroHealth was induced to increase its opioid consumption by Defendants' fraudulent representations of fact and omissions of material fact, MetroHealth suffered actual pecuniary damage. As a result of Defendants' fraud, MetroHealth suffered damages including, but not limited to:

(a) Losses caused by the decrease in funding available for Plaintiff's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

(b) Costs for providing healthcare and medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

(c) Costs for providing healthcare and medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from anoxic brain injury from an opioid overdose;

(d) Costs for providing healthcare and medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from injection-related disease including hepatitis C, heart valve infections and skin infections;

(e) Costs of training physicians, nurse practitioners, physician assistants, and other hospital personnel in the proper methods for prescribing opioid pain medication and for treatment of opioid overdoses and addiction;

(f) Costs associated with providing the community serviced by MetroHealth with naloxone, an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

(g) Costs for providing mental-health services, treatment, rehabilitation services, and social services to victims of the opioid epidemic and their families;

(h) Costs for providing treatment of infants born with opioid-related medical conditions, or born dependent on opioids due to drug use by mother during pregnancy; and

(i) Unrecouped or unreimbursed costs of providing medical treatment to Cuyahoga County's indigent sick and disabled.

528. Defendants' conduct was willful, wanton, and malicious, was directed at the public generally, and intentionally disregarded the rights of the Plaintiff.

COUNT VIII
Negligence *Per Se*
(Against All Defendants)

529. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

530. Violations of statutes and regulations support a cause of action for negligence *per se* where the harm sustained by Defendants' statutory or regulatory violations is the type sought to be prevented and the violations proximately caused the Plaintiff's injuries.

531. The Defendants' conduct with regard to marketing and promoting drugs for off-label use of their respective companies' drugs is covered by the FDCA and FCA.

532. The FDCA creates a statutory prohibition against off-label marketing.

533. The FCA creates statutory standards that prohibit a pharmaceutical entity from knowingly presenting a false claim for payment.

534. Off-label marketing by a pharmaceutical company that results in Medicare or Medicaid paying the cost of a prescription drug for use by a patient for an indication that was not FDA-approved, constitutes a violation of the FCA.

535. The Marketing Defendants have each admitted, by way of either guilty plea or settlement of civil claims – and Individual Defendant Kapoor by indictments and pleas to conspiracy to extort bribes from physicians, by a warning letter from the FDA – to engaging in unlawful off-label marketing of their respective opioid prescription medicines.

536. The Marketing Defendants' violations of the statutory standards set forth in the FDCA and FCA, and Ohio law, including but not limited to R.C. 2925.02(A), constitute negligence *per se* under Ohio law.

537. Defendants' violations of the FDCA and FCA were and are a substantial factor in the injuries and damages sustained.

538. It was foreseeable that Defendants' breach of statutory and regulatory laws described herein would result in the damages sustained.

539. Plaintiff seeks economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' negligence *per se*.

540. Plaintiff seeks all legal and equitable relief as allowed by law (except as expressly disavowed herein), including, *inter alia*, injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT IX
Unjust Enrichment
(Against all Defendants)

541. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

542. All Defendants received a material benefit from MetroHealth's expenditure of funds for the purchase of opioid prescriptions for its insured employees and retirees under MetroHealth's workers' compensation and medical benefits plans. This material benefit and profit garnered by Defendants from opioid prescriptions purchased and paid for by Plaintiff and its residents was the expected and intended result of Defendants' conscious wrongdoing.

543. At the time MetroHealth made these expenditures, it did so in reliance and under the belief that it was provided with all the necessary and accurate information regarding the risks and benefits of opioid use. MetroHealth and its patient population relied on the truthfulness and accuracy of Defendants' misrepresentations and omissions to its detriment, because it agreed to confer a benefit on Defendants, which MetroHealth would not have done but for the wrongful conduct of Defendants.

544. Retention of these benefits by each of the Defendants would be unjust.

545. Additionally, it would be inequitable to allow MetroHealth to continue to bear the cost of expenditures it was forced to make to try to support the health and safety of its patient population, in the face of the opioid epidemic in its community created by all the Defendants, without shifting the full amount of those expenditures from MetroHealth to the Defendants.

VI. PRAYER FOR RELIEF

WHEREFORE, the Plaintiff demands judgment against each Defendant, jointly and severally, awarding Plaintiff the following:

A. Entering a finding that, by their acts alleged herein, Defendants violated the federal and Ohio state laws cited above;

B. Entering a finding and judgment that by the acts alleged herein the Defendants have created a public nuisance;

C. Awarding Plaintiff actual compensatory damages in an amount sufficient to compensate Plaintiff for all its damages as proven at trial;

D. Awarding all statutory damages, including punitive damages;

E. Ordering all Defendants to disgorge all wrongfully retained enrichment for the benefit of the Plaintiff;

F. Enjoining Defendants, their employees, officers, directors, agents, successors, assignees, predecessors, parent or controlling entities, subsidiaries, and all heirs, beneficiaries and assigns of Individual Defendants, and any other person acting in concert with any of the above from continuing to engage in unfair or deceptive practices or continuation of their fraud or negligence in violation of law, and ordering all temporary, preliminary or permanent injunctive relief;

G. Ordering the Defendants to compensate Plaintiff, in full, for past and future costs to abate the ongoing public nuisance that they substantially created in a manner best designed to fund abatement costs for the foreseeable future;

H. Ordering injunctive and equitable relief, as deemed proper by the Court;

I. Awarding Plaintiff reasonable attorneys' fees and all costs and expenses incurred in this litigation;

J. Awarding pre-judgment and post-judgment interest; and

K. All other relief deemed to be appropriate by the Court.

VII. JURY DEMAND

Plaintiff hereby demands a trial by jury on all of the issues herein.

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